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IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF OHIO EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION

MDL No. 2804

This document relates to:

Master Docket No.: 1:17-MD-02804-DAP

THE MUSCOGEE (CREEK) NATION,

Hon. Judge Dan A. Polster

PLAINTIFF,

v.

JURY TRIAL DEMANDED

PURDUE PHARMA L.P., et al.,

DEFENDANTS.

THE MUSCOGEE (CREEK) NATION'S
CONSOLIDATED OPPOSITION TO DEFENDANTS'
MOTIONS TO DISMISS THE NATION'S FIRST AMENDED COMPLAINT

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INTRODUCTION

It is beyond dispute that the opioid industry has caused and is fueling an epidemic of prescription opioid abuse that is ravaging the Muscogee (Creek) Nation (the "Nation") and the rest of the country. Misuse of opioids, already high, has exploded in recent years. Between 1999 and 2016, the number of opioids prescribed across the country quadrupled. Across the United States, the number of people who take prescription opioids for non-medical purposes is greater than the number of people who use cocaine, heroin, hallucinogens, and inhalants combined. Oklahoma, where the vast majority of the Nation's members reside, has the tragic distinction of leading the country in opioid abuse in recent years.

The U.S. Surgeon General has stated that the opioid epidemic has "devastated" communities across America.⁵ "[M]illions of Americans are addicted to prescription opioids, and tens of thousands die annually from opioid overdoses." In 2011, the Centers for Disease Control and Prevention ("CDC") reported that overdose deaths from prescription opioids had reached "epidemic levels." That year, 16,917 people died from a prescription opioid-related overdose, an increase of more than 20 percent over the previous three years. In 2014, 18,893 people died from prescription opioid-related overdoses. By 2015, that number increased again to 22,598. And for every single opioid overdose death, it is estimated that there are 10 more

¹ Am. Compl. \P 2.

 $^{^{2}}$ *Id.* ¶ 5.

³ *Id*. \P 6.

⁴ *Id.* ¶ 7. As stated the in the Complaint, the Nation is a federally recognized and sovereign Indian tribe, with nearly 84,000 members and territory covering 4,867 square miles within the State of Oklahoma. *Id.* ¶ 25. Pharmacies assert that the Nation has misstated the size of its territory, *see* PB at 1 n.2, but on a motion to dismiss, the allegations in a complaint are taken as true. *Eberhard Architects, LLC v. Bogart Architecture, Inc.*, 314 F.R.D. 567, 570 (N.D. Ohio, 2016) (denying motion to dismiss).

⁵ Am. Compl. ¶ 267.

⁶ *Id*. ¶ 2.

⁷ *Id*. ¶ 267.

⁸ *Id.* ¶ 267.

⁹ Am. Compl. ¶ 267.

treatment admissions for abuse, 32 emergency room visits, 130 people who are addicted to opioids, and 825 non-medical users of opioids.¹⁰

Data from the U.S. Substance Abuse and Mental Health Services Administration indicates that more than 194,000 Oklahoma residents use prescription opioids for non-medical purposes. According to the CDC, 2,315 people in Oklahoma died from drug overdoses between 2014 and 2016, and the "main driver[s]" of those deaths were prescription and illicit opioids. Native Americans, including the Nation, suffer the highest per capita rate of opioid overdoses. Pregnant Native American women are up to 8.7 times more likely than pregnant women from other groups to be diagnosed with opioid dependency or abuse. The rate of non-medical opioid use among Native American youths is 60 percent higher than the rate for white youths. The adverse impacts of the opioid epidemic on the Nation cannot be overstated.

The opioid crisis plaguing the Nation did not appear out of thin air, however. It was not caused by a bacteria or virus or spread from animals, insects, or airborne agents. Doctors in Oklahoma did not just wake up one morning and decide to begin writing an excessive number of opioid prescriptions. Although initially the origins of this epidemic were well disguised, they are now no mystery. Manufacturers of prescription opioids poured enormous sums of money into carefully calculated marketing strategies that misstated the risks of opioids. Members of the prescription opioid supply chain utterly failed to meet their duties and legal obligations to prevent diversion. The prescription opioid industry has acted with total disregard for human life

¹⁰ *Id*. ¶ 16.

¹¹ *Id*. ¶ 6.

¹² *Id*. ¶ 2.

¹³ *Id*. ¶ 15.

¹⁴ *Id*. ¶ 19.

¹⁵ *Id*. ¶ 17.

and for the peace, tranquility, and economic well-being of Americans, including the Nation. It must be held accountable.

NATURE OF THE CASE

The Nation brings this action against opioid manufacturers, distributors, and pharmacies to hold them responsible for the injuries they have caused the Nation and its members ("Nation Members" or "Members") by creating and fueling the opioid crisis.

Marketing. Manufacturers of both brand-name and generic prescription opioid products have engaged in, and continue to engage in, a massive marketing campaign that misstates and conceals the risks of treating chronic pain with opioids. That campaign spurred and continues to drive an enormous demand for prescription opioids for non-medical purposes.¹⁶ The campaign enabled manufacturers to overcome the longstanding medical consensus that opioids are highly addictive and, therefore, unsafe for the treatment of chronic pain. This disinformation campaign resulted in a staggering number of opioid users beyond those with legitimate medical needs, leading to alarming rates of addiction.¹⁷ The illicit demand created by manufacturers' dishonest marketing campaign led to the diversion of prescription opioids from the legitimate supply chain to illegitimate channels of distribution and sale. Manufacturers knew or should have known that vast quantities of their addictive drugs were ending up in the hands of Nation Members who do not have a legitimate medical need for them and were particularly vulnerable to addiction.

The Nation's Complaint includes marketing-based claims against manufacturers of both brand-name and generic prescription opioid products (respectively, "Brand-Name

¹⁶ See, e.g., Am. Compl. ¶ 98. 17 See id. ¶¶ 5–6.

Manufacturers" and "Generic Manufacturers"; collectively, "Manufacturers" or "Marketing Defendants"). 18

Diversion. All participants in the legitimate supply chain have duties under federal and common law to prevent the diversion of controlled substances. These entities have disregarded their legal obligations in order to profit from the sale of opioids that they knew or should have known were being diverted to illegitimate channels of distribution and sale.¹⁹

Diversion occurs in a variety of ways. It occurs when companies in the opioid supply chain fail to implement effective systems to detect and investigate suspicious orders. It occurs when manufacturers fill and fail to investigate suspicious orders from distributors, when distributors fill and fail to investigate suspicious orders from pharmacy retailers, and when manufacturers or distributors allow opioids to be lost or stolen from inventory or in transit. It also occurs when pharmacy retailers fill prescriptions despite red flags that indicate that they are not being filled for legitimate medical purposes, and when opioids are stolen by employees or others, obtained through stolen or forged prescriptions, or sold without valid prescriptions. Studies suggest that a substantial number of the opioid prescriptions written in Oklahoma each year are diverted to non-medical uses.²⁰

¹⁸ The Brand-Name Manufacturers are:

Purdue Pharma L.P., Purdue Pharma Inc., and The Purdue Frederick Company (collectively, "Purdue");
 and

[•] Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. (collectively, "Endo").

The Generic Manufacturers are:

[•] Actavis LLC, Actavis Pharma, Inc., Allergan Finance LLC, and Watson Laboratories, Inc. (collectively, "Actavis/Allergan");

[•] Teva Pharmaceuticals USA, Inc. ("Teva");

[•] Amneal Pharmaceuticals ("Amneal"); and

[•] KVK-Tech, Inc. ("KVK-Tech").

¹⁹ *See*, *e.g.*, Am. Compl. ¶ 14.

²⁰ Am. Compl. ¶ 13.

The Nation's Complaint includes diversion-based claims against certain of the manufacturers ("Diversion Manufacturers"),²¹ distributors ("Distributors"),²² and pharmacies ("Pharmacies")²³ (collectively, "Diversion Defendants").

- Amneal; and
- KVK-Tech.

- McKesson Corporation ("McKesson");
- Cardinal Health, Inc. and Cardinal Health 110, LLC (collectively, "Cardinal");
- AmerisourceBergen Corporation and AmerisourceBergen Drug Corporation (collectively, "AmerisourceBergen");
- Walgreens Boots Alliance, Inc. and Walgreen Co. (collectively, "Walgreens");
- Wal-Mart Stores, Inc. ("Walmart");
- SAJ Distributors;
- GCP Pharma LLC;
- Anda Pharmaceuticals Inc. and Anda, Inc. (collectively, "Anda");
- Omnicare Distribution Center LLC ("Omnicare");
- Smith Drug Company;
- The Harvard Drug Group, LLC;
- Pharmacy Buying Association; and
- H. D. Smith, LLC.

²³ The Pharmacies are:

- CVS;
- Walgreens;
- Walmart;
- The Drug Warehouse;
- May's Drug Store;
- Reasor's LLC ("Reasor's");
- Med-X Corporation;
- Economy Discount Pharmacy, Economy Pharmacy, Inc., and Economy Pharmacy Express (collectively, "Economy Pharmacy");
- City Drug Co. and City Drug of Coweta, Inc. (collectively, "City Drug");
- Spoon Drugs, Inc. ("Spoon");
- Carefirst Pharmacy, Inc. ("Carefirst");
- Cityplex Pharmacy ("Cityplex");
- Couch Pharmacy on Sheridan ("Couch");
- Ernie's Pharmacy & Wellness Center, Inc. ("Ernie's");
- Freeland Brown Pharmacy, Inc. ("Freeland");
- Gaddy Discount Drug, Inc. ("Gaddy");
- Getman-Apothecary Shoppe, Inc.;
- Langsam Health Services, LLC;
- M & D Star Drug, Inc. ("M&D");
- Med-Econ Drug, Inc. ("Med-Econ");
- Olympia Pharmacy;
- Pippenger Pharmacies LLC ("Pippenger"); and
- Rogers Drug Co. Inc. ("Rogers").

As discussed below, *see* n.33, *infra*, CVS and Walgreens challenged personal jurisdiction with regard to CVS Health Corporation and Walgreens Boots Alliance, Inc. The Nation has mooted those motions by filing its Unopposed

²¹ The Diversion Manufacturers are:

²² The Distributors are:

The Complaint includes a total of 10 counts, including three federal statutory claims and seven state law claims.

Federal Statutory Claims	
Count I	RICO – Opioid Marketing Enterprise (against Manufacturers/Marketing Defendants)
Count II	RICO – Opioid Supply Chain Enterprise (against all Defendants)
Count III	Lanham Act (against all Defendants)
State Law Claims	
Against Manufacturers/Marketing Defendants	
Count IV	Nuisance
Count V	Negligence and Negligence Per Se
Count VI	Unjust Enrichment
Against Diversion Defendants	
Count VII	Nuisance
Count VIII	Negligence and Negligence Per Se
Count IX	Unjust Enrichment
Against All Defendants	
Count X	Civil Conspiracy

The Nation brings this action both in its *parens patriae* capacity (to protect its quasi-sovereign interests, including its interest in the economy and its Members' health, safety, and welfare) and in its proprietary capacity (to seek redress for injuries to the Nation's proprietary interests).

The Nation's injuries include the costs of: (a) medical care, therapeutic and prescription drugs, and other treatments for patients suffering from opioid-related addictions, overdoses, or diseases; (b) law enforcement and public safety measures necessitated by the opioid crisis; (c) opioid-related counseling and rehabilitation services; (d) social services and welfare for children whose parents suffer from opioid-related disease or incapacitation; and (e) lost productivity of its citizens and businesses.

Motions to Dismiss CVS Health Corporation and Walgreens Boots Alliance, Inc., which dismiss CVS Health Corporation and Walgreens Boots Alliance, Inc. without prejudice. Unopposed Mot. to Dismiss CVS Health Corp., No. 1:18-op-45459, ECF No. 81; Unopposed Mot. to Dismiss Walgreens Boots Alliance, Inc., No. 1:18-op-45459, ECF No. 82. The other CVS and Walgreens entities named in the Nation's amended complaint (Oklahoma CVS Pharmacy, LLC, CVS Pharmacy, Inc., and Walgreen Co.) remain parties to this action. Thus, the Nation still asserts claims against "CVS" and "Walgreens."

The Nation seeks comprehensive relief from Defendants, including: (a) implementation of corrective communications, actions, and programs under court supervision; (b) actual damages for the increased costs to the Nation's healthcare, criminal justice, social services, welfare, and education systems, as well as the cost of lost productivity and any expenses the Nation has incurred or will incur in the future to abate fully the public nuisance Defendants have caused; (c) disgorgement of all amounts unjustly obtained by Defendants; (d) restitution of all expenditures by the Nation resulting from Defendants' conduct; (e) treble damages; (f) attorneys' fees and costs; and (g) such further relief as justice may require.²⁴

PROCEDURAL HISTORY

The Nation filed its Complaint on April 3, 2018 in the U.S. District Court for the Northern District of Oklahoma, Case No. 18-cv-0180-JHP-JFJ (ECF No. 2). The Nation filed a Notice of a Potential Tag-Along Action to the Judicial Panel on Multidistrict Litigation ("MDL") on the same date. The MDL panel transferred the case to this Court on April 18, 2018, Lead Case No. 17-md-02804-DAP (ECF No. 16), and the case was docketed as Case No. 18-op-45459-DAP (ECF No. 16). The Nation filed a First Amended Complaint ("Complaint") on July 9, 2018 (ECF 19).

Marketing Defendants and Diversion Defendants (collectively, "Defendants") have moved to dismiss the Complaint. Twelve of the Defendants named in the Nation's Complaint have neither moved to dismiss nor filed an answer.²⁵

Defendants filed seven separate motions to dismiss the Nation's Complaint:

• CVS's Motion to Dismiss for Lack of Personal Jurisdiction ("CVS's Motion");²⁶

²⁴ See Am. Compl. at 136–39.

²⁵ Those Defendants are: SAJ Distributors; Anda Pharmaceuticals, Inc.; Anda, Inc.; Smith Drug Company; The Harvard Drug Group, LLC; H. D. Smith, LLC; The Drug Warehouse; May's Drug Store; Med-X Corporation; Getman-Apothecary Shoppe, Inc.; Langsam Health Services, LLC; and Olympia Pharmacy.

²⁶ No. 1:18-op-45459-DAP (N.D. Ohio) ECF No. 43.

- Walgreens' Motion to Dismiss for Lack of Personal Jurisdiction ("Walgreens' Motion");²⁷
- Distributors' Motion to Dismiss ("DB");²⁸
- Amneal's Motion to Dismiss Based on Improper Service, Improper Service of Process, and Lack of Personal Jurisdiction ("Amneal's Motion" or "AB");²⁹
- CareFirst, City Drug, Cityplex, Couch, CVS, Economy Pharmacy, Ernie's, Freeland, Gaddy, M&D, Omnicare, Pippenger, Reasor's, Rogers, Spoon, Walgreens, and Walmart's Motion to Dismiss ("PB");³⁰
- Generic Manufacturers' Motion to Dismiss ("GB");³¹ and
- Marketing Defendants' Motion to Dismiss ("MB"). 32

The Nation and the respective Defendants have mooted CVS's Motion and Walgreens' Motion.³³ In order to comply with the Court's instruction to consolidate briefing to the extent possible and for the sake of efficiency, the Nation responds to all outstanding arguments in the motions to dismiss in this Consolidated Opposition.³⁴

²⁷ No. 1:18-op-45459-DAP (N.D. Ohio) ECF No. 48.

²⁸ No. 1:18-op-45459-DAP (N.D. Ohio) ECF No. 49.

²⁹ No. 1:18-op-45459-DAP (N.D. Ohio) ECF No. 50.

³⁰ No. 1:18-op-45459-DAP (N.D. Ohio) ECF No. 52.

³¹ No. 1:18-op-45459-DAP (N.D. Ohio) ECF No. 55.

³² No. 1:17-md-02804-DAP (N.D. Ohio) ECF No. 933.

³³ CVS's Motion challenged personal jurisdiction only with regard to CVS Health Corporation. The Nation has mooted CVS's Motion by filing its Unopposed Motion to Dismiss CVS Health Corporation, which dismisses CVS Health Corporation without prejudice, No. 1:18-op-45459-DAP (N.D. Ohio) ECF No. 81. The other two CVS entities named in the Nation's amended complaint (Oklahoma CVS Pharmacy, LLC and CVS Pharmacy, Inc.) remain parties to this action. Thus, the Nation still asserts claims against "CVS."

Walgreens' Motion challenged personal jurisdiction only with regard to Walgreens Boots Alliance, Inc. The Nation has mooted Walgreens' Motion by filing its Unopposed Motion to Dismiss Walgreens Boots Alliance, Inc., which dismisses Walgreens Boots Alliance, Inc. without prejudice, No. 1:18-op-45459-DAP (N.D. Ohio) ECF No. 82. The other Walgreens entity named in the Nation's amended complaint (Walgreen Co.) remains a party to this action. Thus, the Nation still asserts claims against "Walgreens."

³⁴ For the Court's reference, attached as Exhibit A is a chart showing where in its brief the Nation has responded to each of the arguments raised by Defendants in their motions.

DENIALS OF MOTIONS TO DISMISS IN RELATED OPIOID CASES

Courts in 12 other opioid cases—eight of which were decided this year alone—considered and rejected arguments that Defendants make here in support of their motions dismiss, including in cases involving some of the Defendants in this action.³⁵

Oklahoma. The most relevant case was brought by the State of Oklahoma in state court against Purdue and other opioid manufacturers. State of Oklahoma ex rel. Hunter v. Purdue L.P., No. CJ-2017-816 (Okla. Dist. Ct. Dec. 6, 2017) ("Okla. Litig.") (Exhibit C). The Oklahoma court held that under Oklahoma law, Oklahoma's petition properly alleged causation and injury, and stated cognizable public nuisance and unjust enrichment claims, which the court held were not subject to federal preemption.³⁶ Inasmuch as the Nation asserts the same claims here, the Oklahoma court's ruling as to those claims has obvious Erie implications for this case, as the decision is not only persuasive authority here, but is the best indication of what Oklahoma law is on the issues to be addressed by the Court.³⁷

In the paragraphs that follow, the Nation summarizes the decisions in the other 11 cases.

New Hampshire. The court held that New Hampshire stated a claim for public nuisance.³⁸ The court also found that (1) the state's claims were not preempted, (2) the state's

³⁵ A chart summarizing the 12 opinions is attached as Exhibit B.

³⁶ The only claim the Oklahoma court dismissed was a consumer fraud claim that has not been asserted by the Nation. Because the court's Order does not specifically reference particular claims, but rather generally rejects the remaining arguments raised in defendants' motion to dismiss (which sought to dismiss all of Oklahoma's claims), the particular claims at issue must be determined by reviewing the State's enumeration of its causes of action in its Original Petition, *Hunter*, 2017 WL 8234419, ¶¶ 73–133 (Okla. Dist. Ct. June 17, 2017). The Court may take judicial notice that the petition asserts those claims. *See Granader v. Pub. Bank*, 417 F.2d 75, 82 (6th Cir. 1969) ("Federal courts may take judicial notice of proceedings in other courts of record.").

³⁷ See Staneck v. Greco, 323 F.3d 476, 478 (6th Cir. 2003); Petrovski v. Federal Express Corp., 210 F. Supp.2d 943, 948 (N.D. Ohio 2002).

³⁸ The court dismissed the unjust enrichment claim based on the New Hampshire Supreme Court's declaration that "unjust enrichment generally does not form an independent basis for a cause of action" and because the state failed to "articulate an underlying 'specific legal principle' nor cited authority allowing an unjust enrichment claim to proceed under comparable circumstances." *State of New Hampshire v. Purdue Pharma, L.P.*, 217-2017-CV-00402 (N.H. Super. Ct. Sept. 18, 2018) ("N.H. Litig.") at 28–29. Here, Oklahoma's law of unjust enrichment is substantially broader than in New Hampshire, as it is not limited to quasi-contract actions. *See* § VIII.C, *infra*,

allegations established causation, and (3) the claims were stated with the requisite particularity. Finally, the court found that factual issues precluded any finding, at the motion to dismiss stage, that the counties' claims were time barred. "N.H. Litig

Ohio. The court held that Ohio stated claims for (1) public nuisance under common law and the Ohio Product Liability Act, (2) common law fraud and Medicaid fraud, and (3) violation of the Ohio RICO statute. The court also found that (1) the complaint pled the claims with the requisite particularity, (2) the economic loss rule did not bar the state's damage claims, (3) federal law did not preempt the state's misrepresentation claims, and (4) the complaint did not constitute improper "group pleading." State of Ohio ex rel. Dewine v. Purdue Pharma, L.P., No. 17 CI 261 (Ohio Ct. C.P. Ross Cty. Aug. 22, 2018) ("Ohio Litig.") (Exhibit E).

Alaska. The court held that Alaska stated claims for (1) public nuisance, fraud, negligence, negligent misrepresentation, and unjust enrichment, and (2) strict products liability for design defect and failure to warn. The court also found that (1) the complaint pled the claims with the requisite particularity, (2) the complaint adequately alleged causation, and (3) Purdue's federal preemption argument was premature. The court declined to consider Purdue's statute of limitations argument because it did not appear clearly on the face of the complaint that the claim in question was time-barred. State of Alaska v. Purdue Pharma L.P., No. 3AN-17-09966CI (Alaska Super. Ct. July 12, 2018) ("Alaska Litig.") (Exhibit F).

Certain Counties in New York (manufacturers' motion). The court held that the counties stated claims against manufacturers for public nuisance, fraud, unjust enrichment, and negligence. The court also found that (1) the complaint pled the claims with the requisite particularity, (2) the counties adequately alleged causation, (3) the counties' claims were not

preempted by federal law, (4) the counties' damages were not limited by the economic loss rule or the municipal cost recovery rule, and (5) factual issues precluded any finding, at the motion to dismiss stage, that the counties' claims were time-barred. *In re Opioid Litig.*, No. 400000/2017, 2018 WL 3115102 (N.Y. Sup. Ct. June 18, 2018) ("N.Y. Litig. I").

Certain Counties in New York (distributors' motion). The court held that the counties stated claims against distributors for public nuisance, fraud, unjust enrichment, and negligence. The court also found that (1) the complaint pled the claims with the requisite particularity, (2) the complaint adequately pled causation, (3) the counties' damages were not limited by the economic loss rule or the municipal cost recovery rule, and (4) factual issues precluded any finding, at the motion to dismiss stage, that the counties' claims were time-barred. In re Opioid Litig., No. 400000/2017 (N.Y. Sup. Ct. July 17, 2018) ("N.Y. Litig. II") (Exhibit G).

Washington. The court found that (1) the state's claims against Purdue were not preempted by federal law, (2) the complaint stated claims for nuisance and negligence, (3) the state adequately alleged causation, and (4) the state's damages were not limited by the municipal cost recovery rule. State of Washington v. Purdue Pharma, No. 17-2-25505-0 SEA (Wash. Super. Ct. May 14, 2018) ("Wash. Litig.") (Exhibit H).

Certain Counties in Tennessee. The court held that the counties' allegations (1) met particularity and other pleading requirements, (2) adequately pled causation, and (3) stated valid claims. Staubus v. Purdue Pharma, L.P., No. C-41916, 2018 WL 3349093 (Tenn. Cir. Ct. June 12, 2018) ("Tenn. Litig.").

Missouri. The court held that Missouri's allegations (1) met particularity requirements, and, (2) did not constitute improper "group pleading." *State of Missouri ex rel. Hawley v*.

Purdue Pharma, L.P., No. 1722-CC10626 (Mo. Cir. Ct. Apr. 25, 2018) ("Mo. Litig.") (Exhibit I).

City of Everett, Washington. The court held that (1) defendants owed a common law duty to the City, (2) the City properly pled unjust enrichment and proximate causation, (3) the municipal cost recovery rule did not apply, and (4) the City's claims and damages were not limited by any applicable statute of limitations. City of Everett v. Purdue Pharma, L.P., C14-209RSM, 2017 WL 4236062 (W.D. Wash. Sept. 25, 2017) ("Everett Litig.").

City of Chicago. The court held that the City's allegations met Federal Rule of Civil Procedure 9(b)'s particularity requirement. City of Chicago v. Purdue Pharma L.P., 211 F. Supp. 3d 1058 (N.D. Ill. 2016) ("Chicago Litig.").³⁹

West Virginia. In two opinions, the court held that the state (1) satisfied pleading standards for unfairness claims, (2) had standing to litigate its claims, (3) adequately pled negligence, public nuisance, unjust enrichment, and causation, (4) could use a violation of the state's Controlled Substances Act to form the basis of common law claims, and (5) was not limited by the economic loss or municipal cost recovery rules. State of West Virginia ex rel. Morrisey v. Cardinal Health, Inc., No. 12-C-140 (W. Va. Cir. Ct. Apr. 17, 2015) ("W. Va. Litig. I") (Exhibit J); State of West Virginia ex rel. Morrisey v. Cardinal Health, Inc., No. 12-C-140 (W. Va. Cir. Ct. Feb. 19, 2016) ("W. Va. Litig. II") (Exhibit K).

³⁹ The court dismissed Chicago's unjust enrichment and civil conspiracy claims, as well as its statutory claim for recovery of municipal costs, without prejudice after determining that the City had failed to supply information sufficient to identify certain pharmacies swept up in the City's allegations. The City supplied the information; the case was transferred to this MDL as Case No. 2804; the City filed an amended complaint; and the defendants filed a motion to dismiss, which is pending. In the instant case, the Nation has adequately pled causation with respect to all of its claims. *See* § III, *infra*. Moreover, unlike Chicago, the Nation is not bringing a statutory claim for these damages but instead is including them as a part of its damages claim.

LEGAL STANDARD

Under Federal Rule of Civil Procedure 12(b)(6), a complaint may be dismissed only if a plaintiff fails to allege "enough facts to state claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007).

As this Court stated in *Marek v. Navient Corp.*:

In evaluating a Rule 12(b)(6) motion to dismiss, courts must construe the complaint in the light most favorable to the plaintiff and accept the complaint's allegations as true, drawing all reasonable inferences in favor of the plaintiff.

To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face. A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. The plausibility standard is not akin to a probability requirement, but it asks for more than a sheer possibility that a defendant has acted unlawfully. Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief.

No. 1:17-CV-10120-DAP, 2017 WL 2881606, at *2 (N.D. Ohio July 6, 2017) (Polster, J.) (quoting *Coley v. Lucas Cty., Ohio*, 799 F.3d 530, 537 (6th Cir. 2015)); *see also Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). The Federal Rules of Civil Procedure, particularly Rules 7 through 10, establish a notice pleading system and do not require a detailed statement of all facts necessary to support a claim. "For a claim to be viable, the complaint must, at a minimum, 'give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." *Marie v. Am. Red Cross*, 771 F.3d 344, 364 (6th Cir. 2014) (citation omitted).

ARGUMENT

Defendants' motions to dismiss include general arguments directed to all of the Nation's claims as well as separate arguments directed to specific claims asserted by the Nation. In this Consolidated Opposition, the Nation first addresses Defendants' asserted grounds for dismissal that relate to all of the Nation's claims, including Article III standing, federal preemption,

causation, injury, particularity, group pleading, statutes of limitation, and improper service. The Nation then addresses issues raised by Defendants that are specific to the Nation's state law claims (public nuisance, negligence, unjust enrichment, and civil conspiracy), and the Nation's federal statutory claims (RICO and the Lanham Act). As shown below, none of Defendants' arguments have merit.

I. THE NATION HAS STANDING.

Pharmacies argue the Nation lacks standing to bring this lawsuit.⁴⁰ Pharmacies do so only in one sentence, and merely by cross-referencing their *Summit County* briefing. This half-hearted attempt to make a standing argument is unavailing. Under a standing analysis, a sovereign Indian tribe like the Nation is *not* the same as a political subdivision like Summit County, and has *parens patriae* standing. Therefore, Pharmacies' standing arguments from the *Summit County* briefing have no application here and should be rejected. The Nation also has *Lujan* standing. Thus, Pharmacies' argument fails.

A. The Nation Has Parens Patriae Standing.

As Pharmacies themselves seem to recognize in their *Summit County* briefing, a sovereign entity (like a state) has standing to protect the health and welfare of the public under the *parens patriae* doctrine. This proposition is undoubtedly true. *See Massachusetts v. E.P.A.*, 549 U.S. 497, 519–20 (2007) (holding that the state's right to protect its quasi-sovereign interest satisfies constitutional standing). Pharmacies are wrong, however, to suggest that sovereign status for purposes of *parens patriae* is limited to "the United States or a State." In fact, it is well-established that, in lawsuits to protect public health and welfare of tribal members,

⁴⁰ PB at 2.

⁴¹ See Pharmacies' Memo. in Support of Mot. to Dismiss Compl. at 6, Cty. of Summit v. Purdue Pharma L.P., No. 18-OP-45090 (N.D. Ohio May 25, 2018), ECF No. 497-1 (conceding that "a sovereign—the United States or a State—may bring a parens patriae lawsuit").

Indian tribes are also entitled to invoke *parens patriae* standing as quasi-sovereigns. *See Quapaw Tribe of Okla. v. Blue Tee Corp.*, 653 F. Supp. 2d 1166, 1178 (N.D. Okla. 2009) (collecting cases for the proposition that Indian tribes, like states, have standing to sue to protect quasi-sovereign interests and, therefore, "the requirements of Article III will be satisfied if the Tribe demonstrates that it has *parens patriae* standing"); *Miccosukee Tribe of Indians of Fla. v. United States*, 680 F. Supp. 2d 1308, 1315 (S.D. Fla. 2010) (holding that the Miccosukee Tribe alleged harm to a quasi-sovereign interest that was sufficient to support *parens patriae* standing) *aff'd Miccosukee Tribe of Indians of Fla. v. United States*, 716 F3d 535 (11th Cir. 2013).⁴²

Thus, the question is merely whether the allegations in the Nation's Complaint set forth the elements necessary to invoke *parens patriae* standing. They clearly do. In *Alfred L. Snapp & Son, Inc. v. Puerto Rico*, 458 U.S. 592 (1982), the Supreme Court established three elements that a sovereign must satisfy for *parens patriae* standing. First, the sovereign must "articulate an interest apart from the interests of particular private parties." *Id.* at 607. Second, the sovereign must "express a quasi-sovereign interest" that it seeks to protect for the well-being of its members. *Id.* In discussing this element, the Supreme Court has stated that a quasi-sovereign interest exists "in the health and well-being-both physical and economic-of its residents in general." *Id.* Third, the sovereign must "allege[] injury to a sufficiently substantial segment of its population." *Id.* (noting that there are no "definitive limits" on the proportion of the population that must be adversely affected).

Here, the Nation has articulated quasi-sovereign interests in the health and the physical and economic well-being of citizens that are separate and apart from the private interests of its

 $^{^{42}}$ See also Am. Compl. ¶ 25 ("The Nation is a federally recognized Indian tribe . . . [which] exercises sovereign governmental authority within its territory and over its citizens.").

citizens.⁴³ For example, the Complaint alleges that Defendants' misconduct has damaged the Nation by contributing to social ills such as violence, delinquency, child neglect, family dysfunction, opioid addiction, crime, poverty, property damage, unemployment, decreased productivity, and increased expenditures and diversion of the Nation's resources.⁴⁴ This plainly satisfies the first and second prongs of the *Snapp* test. As to the third prong, the Complaint alleges that Defendants' misconduct has affected all or substantially all of the Nation's Members.⁴⁵ Accordingly, the Nation has adequately alleged *parens patriae* standing under *Snapp*, as that test has been applied to an Indian tribe in *Quapaw Tribe* and cases cited therein.

B. The Nation Has Standing Even Apart From the *Parens Patriae* Doctrine.

Even if the *parens patriae* doctrine did not apply to a sovereign Indian tribe, the Nation's injuries to its own proprietary interests are independently sufficient to confer Article III standing under the analysis set forth in *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992) (setting forth the test for constitutional standing under Article III's "Case or Controversy" clause). To establish this form of Article III standing, a plaintiff must allege it has suffered a concrete and particularized injury that is fairly traceable to the defendant, and that it is likely that a favorable decision will redress that injury. *Id.* at 560–61.

The Nation's allegations satisfy this test. Specifically, the Nation alleges it has suffered a concrete and particularized injury traceable to Defendants because, among other things, the Nation has made (and continues to make) expenditures to address the opioid crisis caused by

⁴³ See generally id. ¶¶ 20, 21, 294 (alleging that Defendants' misconduct has damaged the Nation by contributing to social ills such as violence, delinquency, child neglect, family dysfunction, opioid addiction, crime, poverty, property damage, unemployment, decreased productivity, and increased expenditures and diversion of the Nation's resources)

⁴⁴ See generally Am. Compl. ¶¶ 20, 21, 294.

⁴⁵ See id. ¶¶ 15–22.

⁴⁶ See id. ¶ 27 (alleging that the Nation "bring[] this action in its proprietary capacity and under its *parens patriae* authority").

Defendants.⁴⁷ The Nation has also alleged that Defendants' conduct caused public blight and damage to the Nation's own property rights.⁴⁸ These kinds of injuries fall within the heart of traditional injuries-in-fact that are sufficient to confer Article III standing. *See, e.g., Bank of Am. Corp. v. City of Miami*, 137 S. Ct. 1296, 1303 (2017) (holding that the City's claims of financial injury caused by lost tax revenue and extra expenditures were sufficient to establish standing). Finally, the Nation has alleged sufficient facts to establish that the Nation's injuries are fairly traceable to, and were proximately caused by, Defendants' misrepresentations and negligence.⁴⁹ Thus, Pharmacies' arguments on Article III standing fail.

II. THE NATION'S CLAIMS ARE NOT PREEMPTED.

A. The Nation's Misrepresentation Claims Are Not Preempted.

The Nation alleges state law claims that are based on Manufacturers' marketing misconduct—specifically, their campaign to mislead the public about the health consequences of opioids (hereafter referred to as "misrepresentation claims") based on two different types of conduct. It alleges that Brand-Name Manufacturers said things that they were not permitted to say because they misled physicians and patients about the benefits and risks of opioids, 50 misrepresented the risks of addiction to prescription opioids, 51 misleadingly claimed that patients who were showing signs of addiction were not actually addicted, 52 and falsely claimed that there was no risk in increasing opioid dosages to treat chronic pain. 53 Conversely, it alleges that Generic Manufacturers had a duty—and breached that duty—to counter misstatements and misrepresentations made by Brand-Name Manufacturers, so as to ensure that the FDA-approved

⁴⁷ See id. ¶¶ 21, 22.

⁴⁸ See id.

⁴⁹ See § VIII.B; see also Am. Compl. ¶¶ 406, 443, 476.

⁵⁰ Am. Compl. ¶¶ 44–66.

⁵¹ *Id.* ¶¶ 102–15

⁵² *Id.* ¶¶ 116–119

⁵³ *Id.* ¶¶ 120–25

label information and warnings were effectively communicated to physicians and patients, and not undermined by propaganda from Brand-Name Manufacturers.⁵⁴

Manufacturers assert that the Nation's state law claims are preempted because they would conflict with federal law. Courts in six pending opioid cases, including an Oklahoma court, have rejected this argument.⁵⁵ This Court should do so as well.

Manufacturers basically assert that the Nation's state law negligence and nuisance claims conflict with federal law because the claims supposedly would require Manufacturers to give new or different opioid warnings that the FDA did not or would not approve. But the Manufacturers are proceeding from a false premise. The Nation does *not* claim that Manufacturers were negligent for failing to give new or stronger warnings about their products. In fact, the Nation's Complaint does not challenge the adequacy of the FDA-approved label at all.

1. The Nation's Claims Against Brand-Name Manufacturers Are Not Preempted.

The Nation asserts that Brand-Name Manufacturers were negligent because, among other things, they misrepresented the risks of addiction to prescription opioids,⁵⁷ misleadingly claimed that patients who were showing signs of addiction were not actually addicted,⁵⁸ and falsely claimed that there was no risk in increasing opioid dosages to treat chronic pain.⁵⁹ Separately, the Nation alleges that Generic Manufacturers were negligence for failing to communicate the

⁵⁴ See id. ¶ 158.

⁵⁵ See Okla. Litig. at 1 (Ex. C); N.Y. Litig. I, 2018 WL 3115102, at *5–9; Ohio Litig. at 6 (Ex. E); Alaska Litig. at 15 n.65 (Ex. F); Wash. Litig. at 2 (Ex. H); N.H. Litig. at 7 (Ex. D).

⁵⁶ MB at 45–48. The FDA permits a brand-name manufacturer "to unilaterally strengthen its warning" without prior FDA approval. *See Wyeth v. Levine*, 555 U.S. 555, 568–74 (2009); GB at 15. The FDA prohibits a generic manufacturer from revising its label without prior FDA approval. *See Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472 (2013); *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011).

⁵⁷ Am. Compl. ¶¶ 102-15.

⁵⁸ *Id*. ¶¶ 116–19.

⁵⁹ *Id*. ¶¶ 120–25.

FDA-approved warnings to physicians and patients effectively and adequately—despite the knowledge on the part of Generic Manufacturers that physicians and patients were relying on false information about the health consequences of their opioid products.⁶⁰

Even if the Nation sought to hold Brand-Name Manufacturers liable for not giving new warnings, rather than for misrepresenting the benefits and risks of opioid use, Brand-Manufacturers have not met, and cannot even begin to meet, their burden, on their motion to dismiss, to show that the FDA would not approve the new warnings the Nation hypothetically seek. Courts overwhelmingly decide failure-to-warn claims on the basis of an evidentiary record. Courts overwhelmingly decide failure-to-warn claims on the basis of an evidentiary record.

In Wyeth v. Levine, 555 U.S. 555 (2009), the Supreme Court rejected the argument that common-law claims "stand as an obstacle to the accomplishment of Congress' purposes in the FDCA[.]" *Id.* at 581, and that the FDA "should be 'presumed to have performed a precise balancing of risks and benefits . . . that leaves no room for different state-law judgments[,]" *Fulgenzi*, 711 F.3d at 584. Wyeth affirmed the principle, as the Sixth Circuit stated in Yates v.

⁶⁰ *Id*. ¶¶ 157–61.

⁶¹ Failure-to-warn and misrepresentation have been recognized as separate torts in FDA preemption cases. *See Cerveny v. Aventis, Inc.*, 855 F.3d 1091, 1108–09 (10th Cir. 2017) (remanding to district court because FDA preemption analysis failed to distinguish failure-to-warn claims from fraud claims, negligent misrepresentation, and breach of warranty); *McDaniel v. Upshur-Smith Pharm., Inc.*, 229 F. Supp. 3d 707, 713 (W.D. Tenn. 2017) ("State claims of fraud and deceit do not provide requirements in conflict with [FDA] requirements."), *aff* d, 893 F.3d 941 (6th Cir. 2018).

⁶² See, e.g., Rheinfrank v. Abbott Labs., Inc., 680 F. App'x 369, 375 (6th Cir. 2017) (denying pre-trial summary judgment because "questions of material fact remained"; granting post-trial summary judgment based on "evidence in the record"); Yates v. Ortho-McNeil-Janssen Pharm., Inc., 808 F.3d 281 (6th Cir. 2015) (summary judgment); Strayhorn v. Wyeth Pharm., Inc., 737 F.3d 378 (6th Cir. 2013) (same); Wimbush v. Wyeth, 619 F.3d 632 (6th Cir. 2010); Wright v. Medtronic, Inc., 81 F. Supp. 3d 600, 616 (W.D. Mich. 2015) (denying motion to dismiss fraud claim because "placing this case in proper posture for resolution is in the interest of justice"); Willis v. Abbott Labs., No. 1:15-cv-00057-JHM, 2017 WL 5988215 (W.D. Ky. Dec. 1, 2017) (denying summary judgment on misrepresentation claims based on review of evidentiary record); Kiker v. SmithKline Beecham Corp., No. 2:14-cv-2164, 2016 WL 8189286, at *21 (S.D. Ohio Dec. 15, 2016) (same); but see In re Darvocet, Darvon, and Propoxyphene Prods. Liab. Litig., 756 F.3d 917 (6th Cir. 2014) (on motion to dismiss). Federal law allows Brand-Name Manufacturers to revise brand-name opioid warnings without prior FDA approval. See Wyeth v. Levine, 555 U.S. 555, 568–74 (2009); see also Fulgenzi v. PLIVA, Inc., 711 F.3d 578, 581 (6th Cir. 2013) ("Branded-drug companies, therefore, are free to update their labeling, subject only to subsequent FDA disapproval.").

Ortho-McNeil-Janssen Pharm., Inc., 808 F.3d 281 (6th Cir. 2015), that "plaintiffs injured by brand-name prescription drugs retain state-law tort remedies against the manufacturer of those drugs, provided it is not impossible for the drug manufacturer to comply with both state and federal law[.]" Id. at 294.

Most important, *Wyeth* held that "absent clear evidence that the FDA would not have approved" the warning requested by a plaintiff, a court "will not conclude that it [is] impossible for [a] manufacturer to comply with both federal and state requirements[.]" 555 U.S. at 571; *see also In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, 852 F.3d 268, 286 (3d Cir. 2017) (holding that decision whether failure-to-warn claims are preempted will generally require jury fact-finding), *cert. granted sub nom.*, *Merck Sharp & Dohme Corp v. Albrecht*, 138 S. Ct. 2705 (2018) (Mem.).

In Fosamax, the Third Circuit stated its understanding of "clear evidence":

The term 'clear evidence' ... does not refer directly to the *type* of facts that a manufacturer must show, or to the circumstances in which preemption will be appropriate. Rather, it specifies how difficult it will be for the manufacturer to convince the factfinder that the FDA would have rejected a proposed label change. The manufacturer must prove that the FDA would have rejected a warning not simply by a preponderance of the evidence, as in most civil cases, but by 'clear evidence.'

852 F.3d at 285. The court defined "clear evidence" as "evidence indicating that the thing to be proved is highly probable or reasonably certain." *Id.* at 286.

In a quixotic attempt to meet this demanding standard on a motion to dismiss, Brand-Name Manufacturers attach to their motion a 2013 letter from the FDA to Physicians for Responsible Opioid Prescriptions ("PROP"), responding to a 2012 petition by PROP seeking changes in opioid warning labeling. Brand-Name Manufacturers suggest that this letter is "clear evidence" that the FDA would not have approved the label changes that Marketing Defendants erroneously suppose the Nation seeks through this litigation. The FDA letter does not come

close to constituting "clear evidence" nor even match the record that the *Wyeth* and *Fosamax* courts found insufficient to find preemption.

Defendants have submitted this letter over and over in the opioid cases, including in the Oklahoma case, but the courts in those cases have been uniformly unimpressed. The court in the New York litigation "conclude[d] that, under the circumstances, the FDA's 'less-than-definitive determination' concerning PROP's request for maximum dosage and treatment duration does not meet the *Wyeth* standard of clear evidence . . . that the [FDA] would have rejected proposals from the drug manufacturers to change their labeling" *N.Y Litig. I*, 2018 WL 3115102, at *9 (citation omitted).

In short, the Court should deny Brand-Name Manufacturers' motion to dismiss the Nation's state-law claims against them as preempted.

2. The Nation's Misrepresentation Claims Against Generic Manufacturers Are Not Preempted.

The Nation does not assert that Generic Manufacturers should have provided label warnings different from those required by the FDA. Rather, the Nation alleges:

Specifically, [Generic Manufacturers] failed to ensure that the warning language and other information was effectively communicated to physicians and patients—including by means of communication that did not require language different from the approved FDA label, and did not require permission or assistance from the FDA, such as sending doctors and healthcare providers letters that did not contain additional or substantial new warning information, but which highlighted and explained the products' warnings, labeling, and other information. ⁶³

That such a claim is not preempted follows from the Sixth Circuit's decision in *Fulgenzi* v. *PLIVA*, *Inc.*, 711 F.3d 578 (6th Cir. 2013). That case involved Reglan, a gastroesophageal reflux disease medication. The FDA had replaced one Reglan label warning with another, a

⁶³ Am. Compl. ¶ 158.

"black box" warning. The plaintiff, Fulgenzi, was taking the generic version of the medication, manufactured by PLIVA, after the new label warning was approved, but while PLIVA's generic version still carried the superseded warning. The Sixth Circuit held that federal law did not preempt a failure-to-warn claim by Fulgenzi that PLIVA was liable for not communicating the new label warning, insofar as Fulgenzi alleged that her use of the generic version of the drug, absent such information, was a proximate cause of her injury. The Court stated:

Fulgenzi does not fail to properly state a claim. Fulgenzi alleges that PLIVA's use of the old warning ("Therapy longer than 12 weeks has not been evaluated and cannot be recommended.") instead of adding the updated one ("Therapy should not exceed 12 weeks in duration.") was unreasonable, and the proximate cause of her injuries. At the motion-to-dismiss stage, it is sufficiently plausible that the use of a neutral warning disavowing approval instead of a bold-faced warning affirmatively discouraging long-term use proximately caused Fulgenzi's injury. Whether in fact these allegations are true is a matter for further proceedings.

Id. at 588 (boldface in "black-box" warning).

If federal law did not preempt Fulgenzi's claim that PLIVA was liable for failing to communicate—adequately and effectively—the updated FDA-approved warning (without changing its labeling), it follows that federal law does not preempt the Nation's claims that Generic Manufacturers are liable for failing to communicate effectively and adequately to physicians and patients, through "Dear Doctor" letters or other communications, the *current* FDA-approved warning.⁶⁴

In *Teva v. Superior Court*, 158 Cal. Rptr. 3d 150 (Cal. Ct. App. 2013), the California Court of Appeal, applying *Fulgenzi*, upheld just such an approach in a failure-to-warn case brought by a generic manufacturer. In that case, the court held that federal regulations do not

⁶⁴ The Sixth Circuit has distinguished *Fulgenzi* from cases in which the plaintiff sought to hold a generic manufacturer liable for not supplying content beyond the content of FDA-approved labels. *See McDaniel v. Upsher-Smith Labs.*, *Inc.*, 893 F.3d 941, 946–47 (6th Cir. 2018); *Strayhorn v. Wyeth Pharms.*, *Inc.*, 737 F.3d 378, 399 (6th Cir. 2014), and characterized its holding in *Watson v. Mylan Pharms.*, *Inc.*, 701 F. App'x. 729, 731 (10th Cir. 2017); *see also Hendricks v. Pharmacia Corp.*, No. 2:12-cv-00613, 2014 WL 2515478, at *8 (S.D. Ohio June 4, 2014), *report and recommendation adopted*, 2014 WL 4961550 (S.D. Ohio Oct. 2, 2014).

prohibit a generic drug manufacturer from sending out "Dear Doctor" letters or other communications to doctors about its generic drug products, so long as the information in the communication is also contained in the name-brand product label. Citing *Fulgenzi*, the *Teva* court looked at the specifics of what the plaintiff alleged the defendant should have done and determined that, at least with respect to providing information that was contained in the brand-name label, the plaintiff's claims were not preempted. 158 Cal. Rptr. 3d at 156–60. When Teva thereafter sought review in the U.S. Supreme Court, the Solicitor General submitted an *amicus* brief endorsing this position and opposing review.⁶⁵

B. The Nation's Diversion Claims Are Not Preempted.

Generic Manufacturers also argue that the Nation's diversion claims against them are preempted because federal law gives the federal government exclusive authority to enforce diversion law and—they assert—the Nation is attempting to enforce those laws through its claims. Or, in their words, the Nation's diversion claims "are no more than fraud-on-the-DEA claims," and so are preempted under *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001).⁶⁶ This is simply wrong: the Nation's claims are not "fraud-on-the-DEA" claims at all. Far from suing Generic Manufacturers for failing to comply with their obligations under the Federal Controlled Substances Act ("FCSA") (including, *inter alia* their duty to report suspicious orders), the Nation is suing them for failing to comply with their state-law obligations to use due care in supplying dangerous opioid narcotics. *See generally* § VIII, *infra*. To the extent that the FCSA provides or demonstrates Generic Manufacturers' standard of care, the failure to report to the DEA may be a part of that standard, but the Nation is not suing them for violating the FCSA

⁶⁵ Teva Pharm. USA, Inc. v. Super. Ct. of Cal., Orange Cty., No. 13-956, 2014 WL 7169712, *20–22 (U.S. Dec. 16, 2014).

⁶⁶ GB at 23.

nor for "defrauding" the DEA. *See Fulgenzi*, 711 F.3d at 587 (holding that a claim that is not premised on a violation of federal law, but rather on an independent state duty, such that breach arises from the same act, but with a different legal basis, is not preempted under *Buckman*). Moreover, in light of the FSCA's broad anti-preemption provision, it is far from clear that the DEA has been given the kind of exclusive enforcement authority necessary to give rise to *Buckman* preemption. *See* 21 U.S.C. § 903 ("No provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision of this subchapter and that State law so that the two cannot consistently stand together.").

For these reasons, the Court should deny Generic Manufacturers' motion to dismiss the Nation's state-law claims against them as preempted.

III. THE COMPLAINT ADEQUATELY ALLEGES CAUSATION.

Defendants argue that the Nation fails to allege causation because the Nation's injuries supposedly are insufficiently direct—that is, Defendants contend that intervening causes, including actions of doctors and criminals, break the causal chain.⁶⁷ Defendants are not entitled to dismissal for three reasons. First, causation is a fact question for a jury and cannot be resolved on a motion to dismiss. Second, the Nation has more than adequately alleged a causal connection between Defendants' conduct and the Nation's injuries. Third, the causal chain was

⁶⁷ MB at 4–8, 10–15; DB at 21–23; PB at 4–7; see GB at 22–23.

not broken by the actions of doctors and criminals, which were fully foreseeable by Defendants and therefore do not constitute intervening causes do not excuse Defendants from liability.⁶⁸

A. Under Oklahoma Law, Causation Is Typically a Fact Question and Is Not Resolved on a Motion to Dismiss.

As an initial matter, Oklahoma law provides that causation is a fact question typically left for the jury "unless there is no evidence from which the jury could find a causal nexus" between defendants' wrongdoing and plaintiff's resulting injuries. *Tomlinson v. Love's Country Stores*, *Inc.*, 854 P.2d 910, 916 (Okla. 1993); *see*, *e.g.*, *Bowman v. Presley*, 212 P.3d 1210, 1222 (Okla. 2009) (holding that reliance in fraud claims is "reserved for the trier of fact"); *Delbrel v. Doenges Bros. Ford, Inc.*, 913 P.2d 1318, 1322, (Okla. 1996) ("Whether or not the actions of the appellee were the proximate cause of the injury to the appellant, or merely established a condition is a fact question, and therefore one for the jury to decide."). ⁶⁹ As discussed at length in the next section, the Nation has pled facts that, accepted as true, adequately establish the requisite causal connection between Defendants' fraudulent conduct and the Nation's injuries. For this reason alone, Defendants' causation arguments should be rejected.

⁶⁸ In connection with their intervening cause argument, Pharmacies separately rely on *McClelland v. Harvie Kothe-Ed Rieman*, *Post No. 1201*, *Veterans of the Foreign Wars of U.S., Inc.*, 770 P.2d 569 (Okla. 1989), to argue that Oklahoma's "sole efficient legal cause" doctrine bars the Nation's claims because "intentional misuse of an intoxicating product is, as a matter of law, the only legally relevant cause of resulting injuries." PB at 4. This argument fails outright. Not only does that case present a completely different fact pattern than the case *sub judice* (i.e., a bar's liability for a patron's drunk diving), the *McClelland* court also held that such rule applies only to those claims arising prior to October 3, 1986. *McClelland*, 770 P.3d at 572; *see Brigance v. Velvet Dove Restaurant,Inc.*, 725 P.2d 300, 304 (Okla. 1986) (for claims after 1989, a commercial vendor "has a duty to exercise reasonable care not to sell liquor to a noticeably intoxicated person"). In any event, that rule is not the standard here.

⁶⁹ See also City of New York v. Beretta U.S.A. Corp., 315 F. Supp. 2d 256, 281 (E.D.N.Y. 2004) ("Satisfaction of the

causation requirement for liability in public nuisance actions requires proof that a defendant, alone or with others, created, contributed to, or maintained the alleged interference with the public right. Whether specific acts or omissions meet this standard involves a fact-intensive inquiry, making it difficult to resolve the issue on a motion to dismiss on the pleadings." (citations omitted)); *People v. ConAgra Grocery Prods. Co.*, 17 Cal. App. 5th 51, 104, 227 Cal. Rptr. 3d 499, 545–46 (2017), *petition for cert. docketed*, No.18-84 (U.S. July 18, 2018), *petition for cert. docketed*, No. 18-86 (U.S. July 18, 2018) ("Defendants argue that they should be absolved of responsibility for the current hazard because their wrongful conduct was 'too remote' and 'attenuated' from the current hazard. This was a question of fact for the trial court... the trial court could have reasonably concluded that defendants' promotions, which were a substantial factor in creating the current hazard, were not too remote to be considered a legal cause of the current ... nuisance.").

B. The Nation Has Adequately Alleged a Casual Connection Between Defendants' Actions and Omissions and the Resulting Injuries.

Defendants argue the Nation failed to plead a direct link between Defendants' fraudulent conduct and the Nation's injuries.⁷⁰ This assertion is contrary to Oklahoma law.

Under Oklahoma law, proximate cause is "the efficient cause that sets in motion the chain of circumstances leading to an injury[.]" *Tomlinson*, 854 P.2d at 915–16. The Oklahoma Uniform Jury Instructions further define proximate cause as "a cause which, in the natural and continuous sequence, produces an injury and without which the injury would not have happened." *Id.* at 915 n.6. The Oklahoma Supreme Court has stated that foreseeability "is the standard by which proximate cause . . . is to be tested." *Id.* at 916.

The Nation's allegations more than meet this standard. The Nation alleges—with ample detail—that the Nation's resulting injuries were a foreseeable result of Defendants' acts and omissions. In particular, the Nation alleges that: (1) Marketing Defendants dramatically increased the demand for opioids (and the number of opioid prescriptions) by disseminating false and misleading information about the risks and benefits of these drugs (including, in particular, the risk of addiction);⁷¹ and (2) Diversion Defendants failed to control the supply of dangerous Schedule II drugs.⁷² The Nation also alleges that a result of Defendants' unlawful conduct, the Nation incurred significant costs, including costs for substance abuse treatment services, emergency medical care, law enforcement, the judicial system, and lost productivity of its workforce.⁷³ These damages are precisely the kind of harms that were the foreseeable results of Defendants' misconduct—and they therefore satisfy the standard for pleading proximate cause.

⁷⁰ MB at 4–6; DB at 21–22; PB at 6.

⁷¹ Am. Compl. ¶¶ 102–15.

⁷² *Id.* ¶¶ 200–62.

⁷³ *Id.* ¶ 294.

Disregarding Oklahoma law, Defendants principally rely on *Holmes v. Sec. Inv'r Prot.*Corp., where the U.S. Supreme Court commented in the context of analyzing a plaintiff's statutory standing in a RICO case that "a plaintiff who complain[s] of harm flowing merely from the misfortunes visited upon a third person by the defendant's act [is] generally said to stand at too remote a distance to recover." 503 U.S. 258, 268–69 (1992). In interpreting the RICO statute, the Court identified three policy reasons why directness is an important limitation on a plaintiff's ability to recover under certain federal statutes, such as RICO or the Clayton Act:

(1) "the less direct an injury is, the more difficult it becomes to ascertain the amount of a plaintiff's damages attributable to the violation, "; (2) indirect injuries "would force courts to adopt complicated rules apportioning damages among plaintiffs[,]" thereby risking "multiple recoveries"; and (3) directly injured parties are able to "vindicate the law" by bringing suit for their own damages. *Id.* at 269–70.

First of all, Defendants are wrong to suggest that *Holmes* sets forth an indelible, threshold proximate cause requirement for all causes of action under the common law. That simply is not true. The *Holmes* court addressed proximate cause on a motion to dismiss as part of its analysis of statutory standing (since standing typically is a question appropriate for a motion to dismiss). For common-law claims where the plaintiff's standing cannot be genuinely disputed, as here, the policy considerations in *Holmes* have little relevance.

While the Supreme Court obviously did make some comments in *Holmes* about the "tendencies" of the common law with respect to proximate causation, the Court clearly was not purporting to set forth a rule of common law in general, or of Oklahoma law in particular. So far as it appears, no Oklahoma state court has even cited *Holmes* in a published decision. By contrast, courts have explained in detail why *Holmes*' "proximate cause" analysis does not

necessarily apply to common law claims. *See, e.g., Lerner v. Fleet Bank, N.A.*, 459 F.3d 273, 283–286 (2d Cir. 2006) ("the 'use of no proximate cause language as the ground for dismissal in statutory cases frequently leads to confusion when the issue of proximate cause is raised in related common law claims' because the phrase 'proximate cause' may cover a greater or lesser swath of injuries and victims when used in the statutory context") (citations omitted). *Id.* at 284.

Second, even accepting Defendants' attempt to extend *Holmes* beyond its original context, there is no grounds under Oklahoma law to apply the *Holmes* analysis to a nuisance claim. The *Holmes* court was largely concerned with multiple or duplicative recovery of monetary damages. *See Holmes*, at 271 ("[t]he general tendency of the law, *in regard to damages at least*, is not to go beyond the first step") (emphasis added). The remedy for public nuisance is abatement. Although courts recognize that, in some cases, payment of money may be an aspect of an abatement remedy, the two are not the same. The concerns of the *Holmes* court have no application in the context of a public nuisance claim brought by a sovereign like the Nation.

However, even if the *Holmes* factors applied here to all of the Nation's claims, they actually establish that the Nation has adequately alleged proximate cause. The Nation alleges discrete categories of damages directly attributable to Defendants' misconduct.⁷⁵ The Nation's damages are its own and cannot be sought or recovered by any other plaintiff, thereby eliminating the risk of duplicative recoveries. And the Nation's claims will "vindicate the law"

⁷⁴ Under Defendants' theory that courts must apply a *Holmes*-like "direct injury" test at the motion to dismiss stage, there would be no such thing as a loss of consortium claim, nor a bystander tort (such as negligent infliction of emotion distress), since the injury in these kinds of claims, among others, are derivative or partly derivative of a predicate injury inflicted on someone other than the plaintiff. But these kinds of claims are widely recognized in the common law, because courts do not apply the more ridged proximate cause analysis from the RICO statute to all manner of claims.

⁷⁵ Am. Compl. ¶ 294.

by seeking redress for the harm it has suffered directly in combatting a crisis that has taxed the Nation's healthcare system, law enforcement and public safety organizations, social services, and welfare and criminal justice systems. Thus, *Holmes* and its directness test support denial of Defendants' motions.

In this regard, the Ohio Supreme Court's decision in *City of Cincinnati v. Beretta U.S.A. Corp.*, 768 N.E.2d 1136 (Ohio 2002), *superseded on other grounds by statute*, is particularly instructive. In *Beretta*, the City of Cincinnati alleged that the defendants' negligent marketing and distribution of firearms created an illegal secondary market. *Id.* at 1147–49. The City alleged that, as a direct result of defendants' misconduct, it "suffered 'actual injury and damages including, but not limited to, significant expenses for police, emergency, health, prosecution, corrections and other services.'" *Id.* at 1148. The defendants countered that "the causal connection between the alleged wrongdoing and the alleged harm is too tenuous and remote and . . . the claims asserted are indirect and wholly derivative of the claims of others." *Id.* at 1147. Applying the *Holmes* factors, the Ohio Supreme Court rejected the defendants' arguments and held that: (1) the City's damages could be easily computed; (2) "there [was] little risk of double recovery, since [the City] is seeking recovery for injuries to itself only"; and (3) the City "[was] seeking recovery for its own harm." *Id.* at 1149. Thus, the court held that the City's claims were not too remote to serve as a basis for recovery. *Id.* at 1148.

The same analysis fits squarely here. The Nation alleges that Defendants' misconduct (that is, dissemination of false and misleading information about the risks and benefits of opioids and failure to control the opioids supply chain) created an illegal secondary opioid market and an opioid crisis.⁷⁷ As a foreseeable result, the Nation incurred injuries in the form of increased

⁷⁶ *Id*. ¶ 22.

⁷⁷ Am. Compl. ¶ 98.

government costs it was forced to expend in response to the opioid crisis.⁷⁸ In fact, the Nation's injuries here are even more direct than the City of Cincinnati's in *Beretta* because, unlike those defendants—who legally sold firearms—Defendants here conducted their businesses in violation of multiple federal and state laws.⁷⁹

For the foregoing reasons, the Nation's injuries for all claims are sufficiently direct to establish causation.

C. Intervening Events Do Not Break the Causal Chain.

Defendants also argue that the acts of third parties—physicians who wrote prescriptions for opioids and third parties who engaged in criminal diversion of opioids—break the causal chain between their misconduct and the Nation's injuries.⁸⁰ These arguments fail.

The Oklahoma Supreme Court has recognized that "[n]ot every intervening cause will insulate the original [wrongful] actor from liability." *See, e.g., Minor v. Michael Ben Zidell Trust*, 618 P.2d 392, 394 (Okla. 1980). Instead, to qualify as a superseding cause that cuts off liability for the original wrongdoer, an alleged intervening cause must meet at least three requirements: "(1) it must be independent of the original act (2) it must be adequate of itself to bring about the result and (3) it must not have been a reasonably foreseeable event." *Id.* (footnote omitted). Simply put, the causal nexus between wrongful conduct and resulting injury will only be deemed broken upon "the intervention of a new, independent and efficient cause which was neither anticipated nor reasonably foreseeable." *Id.* And "unless the intervening cause meets these characteristics, the chain of causation, extending from original act to the injury, is not broken." *Id.* (footnote omitted).

⁷⁸ *Id.* ¶ 22.

⁷⁹ Am. Compl. ¶¶ 102–262 (outlining the duties imposed on each class of Defendants and the actions each class of Defendants engaged in to violate those duties under both federal and state law).

⁸⁰ MB at 10–15; DB at 22–23; PB at 5–6.

Here, Defendants could only be relieved of liability for their misconduct if the actions of physicians or criminal actors were wholly independent from Defendants' misconduct, would have been adequate to bring about the opioid crisis on their own, and were not reasonably foreseeable. None of those is true in this case.

With respect to the physicians who prescribed opioids, the Nation alleges that Marketing Defendants misled prescribing doctors by misrepresenting the risks and benefits of opioids and opioid addiction. That these physicians prescribed opioids in accordance with those misrepresentations was the intended, actual, and entirely foreseeable result of Marketing Defendants' misconduct, not a new and independent cause in itself. *See, e.g., In re Neurontin Mktg. & Sales Practices Litig.*, 712 F.3d 21, 39 (1st Cir. 2013) ("Pfizer now argues that because doctors exercise independent medical judgment in making decisions about prescriptions, the actions of these doctors are independent intervening causes. But Pfizer's scheme relied on the expectation that physicians would base their prescribing decisions in part on Pfizer's fraudulent marketing."); *Ileto v. Glock, Inc.*, 349 F.3d 1191, 1208 (9th Cir. 2003) (finding that it was foreseeable that the defendants' distribution system would help to foster an illegal secondary gun market and result in handguns falling into the hands of people who would misuse them);

In fact, Defendants' misleading prescribing guidelines were so successful that the Surgeon General of the United States "expressed concern that 'heavy marketing to doctors' had led many to be 'taught—incorrectly—that opioids are not addictive when prescribed for legitimate pain[.]" Defendants cannot now hide behind these supposedly "intervening causes"

⁸¹ See, e.g., Compl. ¶ 106.

⁸² *Id.* ¶ 112 (citing Letter from U.S. Surgeon General Vivek H. Murthy (Aug. 2016), https://perma.cc/VW95-CUYC).

that they knowingly and intentionally put into motion, and which directly resulted in the Nation's losses.

Nor does the learned intermediary doctrine break the causal chain. Under Oklahoma law, that doctrine only applies when a manufacturer "adequately warns prescribing physicians of the dangers associated with the drug." *Woulfe v. Eli Lilly & Co.*, 965 F. Supp. 1478, 1482 (E.D. Okla. 1997). The doctrine does not apply when the manufacturer misleads and misrepresents the drug's safety—as the Nation alleges is the case here. Moreover, Oklahoma courts will not shield pharmacies from liability "[i]f the prescription [was] 'unreasonable on its face,'" such as in cases—as alleged here—involving "facially bizarre quantities or dosages clearly outside of any acceptable range." *Carista v. Valuck*, 394 P.3d 253, 256 (Okla. Civ. App. 2016). In any case, whether the doctor was "adequately warned" or whether the prescriptions were unreasonable are fact questions for the jury, and are not appropriate on a motion to dismiss.

Nor were the acts of prescribing physicians adequate to have independently caused the opioid crisis on their own. To be clear, the opioid crisis was not caused by rogue prescription-happy physicians acting alone. Rather, the crisis was caused by Defendants' concerted efforts to minimize the risks of their products, to flood the market with opioids and ignore any oversight over their supply chain, and which allowed them to reap the monetary benefit bestowed by an addicted populace. Defendants' argument that prescribing physicians are superseding causes of the opioid crisis ignores these facts.

The foreseeability analysis is the same with respect to individuals participating in the illegal secondary market: their actions do not break the causal chain. The Nation alleges that Diversion Defendants failed to control their supply lines and prevent diversion.⁸³ Similar to the

 $^{^{83}}$ *Id.* ¶¶ 200–262.

foreseeable consequence of the prescribing physicians, the illegal conduct of those engaged in drug abuse and diversion is not independent of Defendants' wrongful conduct. It is the natural result. Indeed, a third party's intentional tort is not a superseding cause when "the actor realizes or should realize the *likelihood* that the third person might commit the tortious act." *Lockhart v. Loosen*, 943 P.2d 1047, 1080 (Okla. 1997). Here, the illegal drug activity Defendants identify was an entirely foreseeable consequence of Defendants' failure to control the opioid supply.⁸⁴

Moreover, widespread addiction was a foreseeable consequence of Marketing

Defendants' misrepresentations that opioids are rarely addictive when taken for chronic pain.

Misuse and abuse becomes even more likely when the public is ignorant of, or, more to the point here, misled as to the danger they pose. Thus, criminal conduct, including abuse and diversion, was an entirely foreseeable consequence. See also City of New York v. Beretta U.S.A. Corp.,

315 F. Supp. 2d 256, 282 (E.D.N.Y. 2004) ("Intervening actions, even multiple or criminal actions taken by third parties, do not break the chain of causation if a defendant could reasonably have expected their nature and effect." (citations omitted)).

Finally, just like prescribing physicians, third-party criminals could not have caused the opioid crisis on their own. Without Defendants' misconduct—including their misrepresentations and oversight/control failures—the nationwide epidemic would not have occurred. Once again, Defendants' argument that various unidentified third-party criminals are superseding causes of the opioid crisis completely ignores their own involvement in marketing and distributing opioids.

⁸⁴ *Id*. ¶¶ 263.

⁸⁵ See id. ¶¶ 109–10.

⁸⁶ Pharmacy Defendants' reliance on *Prince v. B.F. Ascher Co., Inc.*, 90 P.3d 1020 (Okla. Civ. App. 2004), is also distinguishable. In that case, the decedent, "did not use [the drug] for its intended purpose . . ." *Id.* at 1027. "Rather, the product became dangerous only as a result of [his] after-purchase modifications" of the inhaler and the "injection into his veins of a solution made from the [active ingredient] he extracted from [the drug]." *Id.* at 1027, 1029. This is an entirely different fact pattern than the case here. Besides not alleging injuries on behalf of one of its many deceased Members, none of the Nation's damages occurred as a result of after-purchase changes made to Defendants' opioids.

Applying this same standard in other pending opioid cases, other courts have denied motions to dismiss claims on the basis of alleged intervening causes, where Purdue, Endo, and other defendants made arguments similar or identical to those that Defendants assert here. In particular, courts that have considered the matter have specifically rejected arguments that Purdue could not have foreseen that distributors would distribute Purdue's opioids, that doctors would prescribe Purdue's opioids, that pharmacies would fill prescriptions for Purdue's opioids, that Purdue's opioids may be diverted, and that Purdue's opioids may be abused. *See Everett Litig.*, 2017 WL 4236062 at *4–6; *W. Va. Litig. I*, at 19–22 (Ex. J); *W. Va. Litig. II*, at 2, 29 (Ex. K); *Tenn. Litig.*, 2018 WL 3349093, at *3–4.87

The Nation's Complaint is no different. The Nation's injuries were the foreseeable and *intentional* result of Defendants' actions. Marketing Defendants knew that a change in prescribing practices would lead to an increase in opioid usage, so they tailored their message for maximum effect.⁸⁸ Diversion Defendants knew their supply chains were at-risk, and yet routinely filled suspicious orders.⁸⁹ Pharmacy Defendants were on notice that addicted individuals would come seeking opioids for non-medical purposes and yet regularly ignored red flags.⁹⁰ The Complaint adequately alleges foreseeability and causal connection for each group of these Defendants.

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⁸⁷ Although another court did dismiss certain claims (without prejudice) based on a failure to plead causation adequately, the plaintiff in that case had not alleged any connection between the defendants' acts and harm to the plaintiff. *See Chicago Litig.*, 211 F. Supp. 3d at 1082–84. As detailed below, the Complaint here does allege a connection between Defendants' actions and the harm to the Nation and its citizens. *See, e.g.*, Am. Compl. ¶¶ 263–94.

⁸⁸ Am. Compl. ¶¶ 126–28 (alleging that Marketing Manufacturer Defendants targeted their message for maximum effect, establishing front groups and employing key opinion leaders ("KOLs"), doctors paid by the pharmaceutical companies, to push opioids because "they knew that doctors often place great confidence in seemingly independent peers.").

⁸⁹ *Id.* ¶¶ 201–07 (alleging that Diversion Defendants received regular instruction and guidance on suspicious ordering and supply chain integrity from the DEA); *see also* ¶¶ 212–23 (outlining settlements reached by specific Diversion Defendants' for failure to report suspicious orders).

⁹⁰ *Id.* ¶¶ 237–39 (detailing Pharmacy Defendants' receipt of "extensive guidance" from the DEA, state pharmacy boards, and industry associations, on how to flag suspicious orders and non-medical drugseekers); *see also* ¶¶ 245–

At most, these issues are questions of fact that cannot be resolved on a motion to dismiss unless "there is no contrary evidence and 'but one reasonable inference may be drawn from the adduced facts." *Mike v. Prof'l Clinical Lab., Inc.*, 450 Fed. App'x 732, 739 (10th Cir. 2011) (citation omitted). Indeed, "[u]nder Oklahoma law, the foreseeability of an intervening cause is ordinarily a question of fact for the jury." *Id.* Defendants have utterly failed to demonstrate that these intervening causes were so unforeseeable that dismissal of the Nation's claims is warranted as a matter of law.

For the foregoing reasons, this Court should reject Defendants' arguments regarding proximate causation.

IV. THE NATION HAS ADEQUATELY PLED COGNIZABLE INJURY.

Throughout their briefs, Defendants contend that the Complaint should be dismissed because the Nation has failed to allege a cognizable injury. Defendants' position rests on four arguments: (1) the Nation may not recover certain healthcare costs under federal law;⁹¹ (2) the Nation may not recover indirect damages based on its citizens' personal injuries;⁹² (3) under the municipal cost recovery rule, the Nation may not recover the costs of public services;⁹³ and (4) the Nation's claims are barred by the economic loss rule.⁹⁴

None of Defendants' arguments have merit. First, contrary to Defendants' arguments, no aspect of federal law limits the damages the Nation seeks here, and the Nation has not pled a claim under the one statute Defendants invoke. Second, the Nation's injuries are directly traceable to Defendants' misconduct and consist of damages the Nation itself has incurred.

^{56 (}outlining numerous regulatory actions against specific Pharmacy Defendants for their failure to prevent diversion and filling of suspicious orders).

⁹¹ MB at 20–23.

⁹² See, e.g., MB at 5–6, 36.

⁹³ MB at 23.

⁹⁴ GB at 23.

Third, the municipal cost recovery rule has never been adopted by an Oklahoma court, nor do

Defendants cite a single case from anywhere in the country where the rule has been applied

against a Native American Tribe. Finally, Defendants do not cite any Oklahoma authority in

support of their argument that the economic loss doctrine applies, and, in any event, the doctrine

has no application here, because the Nation has not brought a breach of contract claim.

A. Section 1621e of the Indian Health Care Improvement Act Does Not Bar Recovery.

Manufacturers assert that federal law preempts and otherwise bars the Nation's right to recover the costs it incurred to provide healthcare to its citizens and other Native Americans as a result of Defendants' illegal conduct, while also asserting that the healthcare at issue may have actually been provided by the U.S. Indian Health Service ("IHS"). 95

This assertion fails for two reasons. First, the Nation is not attempting to recover for expenses incurred by IHS; instead, it seeks to recover for expenses incurred by the Nation and paid for with Nation funds. Second, the section of the Indian Health Care Improvement Act ("IHCIA") relied upon by Defendants has no impact on the Nation's claims. It neither limits nor preempts state law causes of action against tortfeasors, or federal causes of action under other statutes, and therefore it does not bar the claims the Nation asserts here. Moreover, the Nation is not asserting a claim under the section of the IHCIA that the Defendants invoke, and therefore the requirements of that section are irrelevant. Thus, Defendants' arguments fail.

⁹⁵ Manufacturers' argument on this point does not seek dismissal of any cause of action in its entirety, but rather seeks only to limit the Nation's ability to recover its healthcare expenses. *See* MB at 19 ("The Tribes cannot recover for the costs of providing health care."). Defendants thus do not contend that the IHCIA preempts the Nation from recovering for the many non-healthcare services it has been forced to provide, and will continue to be forced to provide, as a result of Defendants' conduct. *See* Am. Compl. ¶¶ 282, 291, 294.

1. The Nation Seeks to Recover for Care the Nation Itself Provided.

Defendants first assert that the Nation may be seeking to recover for "care provided by the Indian Health Service (IHS)." But that assertion is simply wrong. *All* of the healthcare costs the Nation seeks to recover are costs the Nation *itself* either has incurred or will incur. Defendants' reliance on the New Mexico court's *Acoma Pueblo* decision for the proposition that "[o]nly the United States has standing to recover the cost of any direct expenditures by IHS" is therefore inapposite. In the type of "direct services" situation referred to by Defendants, IHS directly provides healthcare through IHS facilities and personnel. In that situation, it is IHS that incurs the disputed expenses and therefore IHS that has the right to recover such expenses. Here, by contrast, the Nation does not receive, and is not seeking recovery for, any direct service care provided by IHS. Rather, the Nation itself provides healthcare services to its Members using a variety of funds, including funds paid to the Nation pursuant to a compact awarded under Title V of the Indian Self Determination and Education Assistance Act ("ISDEAA"). Funds received under an ISDEAA compact or contract are tribal funds, to be budgeted and spent to provide healthcare as the Tribe deems best. 100

Ultimately, it is the Nation which provides healthcare to its citizens, and it is the Nation, not IHS, which has incurred and will continue to incur the costs of providing that healthcare by

⁹⁶ MB at 20.

⁹⁷ Am. Compl. ¶¶ 272, 282, 291, 294, 431, 443, 464, 476, 481.

⁹⁸ MB at 20 (citing *Acoma Pueblo v. Am. Tobacco Co.*, slip op. at 8–10, No. 99-CV-1049 (D.N.M. July 30, 2001)); see also Ex. B to MB.

⁹⁹ 25 U.S.C. §§ 5301–5423; *see* Am. Compl. ¶ 26. Under the ISDEAA, the IHS, acting through either a contract awarded under Title I of the ISDEAA or a broader compact awarded under Title V, may transfer to a tribe the responsibility for delivering healthcare that would otherwise be provided by the federal government. 25 U.S.C. §§ 5321 (Title I contracts), 5384 (Title V compacts).

Title V compact "in any manner which the Indian tribe deems to be in the best interest of the health and welfare of the Indian community being served"); see also id. (allowing a Tribe to "redesign or consolidate programs" under a Title V compact in any manner it "deems to be in the best interest of the health and welfare of the Lorentz in any manner it "deems to be in the best interest of the health and welfare" of the community being served); cf. 25 U.S.C. §§ 5324(j), 5325(o) (parallel provisions under Title I).

spending tribal funds, be they funds received via its IHS compact or funds received by the Nation from other sources such as taxes, royalties, tribal businesses, contracts, and grants.¹⁰¹ The Nation therefore has standing to recover these costs. ¹⁰²

2. Section 1621e Does Not Bar Recovery for Care the Nation Provided.

Defendants' second assertion is more convoluted but equally wrong. Defendants argue that the Nation cannot recover the cost of providing healthcare because, they assert, Congress in section 206 of the IHCIA, 25 U.S.C. § 1621e(e), prohibited Indian Tribes from seeking damages for "medical costs funded under the ISDEAA," except through the process set forth in section 1621e(e)(3). And that process, they further contend, requires the Nation to name the specific tribal members who suffered the harm underlying the claim, something the Nation did not do here. 104

Defendants are simply wrong about the reach of section 1621e(e)(3). Although that provision does provide an Indian tribe with a federal cause of action against tortfeasors to recover certain healthcare costs, it nowhere purports to displace or restrict tribal rights to recover such costs through other available causes of action, such as state law tort claims or other federal statutory rights of action. To the contrary, section 1621e supplements and builds upon such other rights of recovery by arming Tribes with a new federal cause of action as an <u>additional</u>

¹⁰¹ Am. Compl. ¶ 262, 272, 282, 291, 294, 431, 443, 464, 476, 481.

¹⁰² Defendants do not dispute that the Nation can recover funds that it received pursuant to its ISDEAA compact and spent on healthcare. *See* MB at 20–23. The short, unpublished *Acoma Pueblo* decision—cited by Defendants for a different proposition—briefly mentioned contract funds, but the decision does not analyze the ISDEAA and is therefore unhelpful on the issue. *Acoma Pueblo*, at 5, 8.

¹⁰³ MB at 21. Defendants recognize that their argument, at best, applies only to the portion of the Nation's healthcare costs funded under the ISDEAA. *Id.* at 21–23. These arguments, as noted earlier, therefore have no impact on the Nation's ability to recover for the enormous healthcare costs the Nation has funded from other sources, such as taxes, royalties, tribal government enterprises (including gaming revenues), grants, and so forth. Am. Compl. ¶¶ 272, 282, 291, 294, 431, 443, 464, 476, 481.

¹⁰⁴ MB at 21–23.

weapon to pursue responsible parties. This is made plain, both by its text and its legislative history.

Subsection 1621e(e)(3)(A)—the focus of Defendants' motion with respect to this issue—provides that tribes and tribal healthcare providers operating programs transferred to a tribe under the ISDEAA may avail themselves of the same right of action against tortfeasors that Congress provided to the federal government under the Federal Medical Care Recovery Act ("MCRA") 42 U.S.C. § 2651 *et seq.* In cases in which a Tribe or tribal organization furnishes services to a patient "who is injured or suffers a disease on or after March 23, 2010, under circumstances that establish grounds for a claim of liability against the tortfeasor with respect to the injury or disease," subsection (e)(3)(A) gives the Tribe or tribal organization "a right to recover from the tortfeasor (or an insurer of the tortfeasor) the reasonable value of the health services so furnished . . . in accordance with [MCRA], to the same extent and under the same circumstances as the United States may recover under that Act." 105 25 U.S.C. § 1621e(e)(3)(A).

Defendants argue that Section 1621e(e) "governs" the Nation's claims for healthcare damages funded under the ISDEAA, leaving the Nation with "no [other] remedy" for these damages. ¹⁰⁶ For this to be true, section 1621e(e) would have to preempt or displace all other remedies available to the Nation for recovery of such funds under state and other federal law. But, decisively, section 1621e(e) does no such thing.

Looking first at the statutory text, Section 1621e contains no language expressly preempting other remedies available to tribes and tribal healthcare providers. ¹⁰⁷ Indeed, the text

¹⁰⁵ Although subsection 1621e(a) contains a second cause of action which operates independent of MCRA, Defendants largely ignore it.

¹⁰⁶ MB at 21.

¹⁰⁷ Among its several formulations of preemption doctrine, the Supreme Court has stated that federal law preempts state law in three circumstances. First, by express preemption, where Congress has explicitly defined the extent to which its enactments pre-empt state law. Second, implied preemption (also known as "field preemption"), where Congress regulates conduct in a field that it intended the federal government to occupy exclusively. Finally, conflict

does just the opposite: it contains a *savings* clause in subsection (k), expressly providing that "[n]othing in this section shall be construed to limit any right of recovery available to the United States, an Indian tribe, or tribal organization under the provisions of any applicable, Federal, State, or tribal law" 25 U.S.C. § 1621e(k). Curiously, Defendants overlook this provision.

Furthermore, if subsection (k) was not clear enough, subsection (c) expressly provides that section 1621e preempts state law only to the extent that state law would <u>limit</u> a tribe's right of recovery provided by section 1621e(a):

No law of any State, or of any political subdivision of a State and no provision of any contract, insurance or . . . other health care plan or program entered into or renewed after November 23, 1988, shall prevent or hinder the right of recovery of the United States, an Indian tribe, or tribal organization under subsection (a).

25 U.S.C. § 1621e(c) (emphasis added). This language—likewise overlooked in Defendants' motion—establishes beyond reasonable debate that section 1621e operates as a floor, not a ceiling, on a Tribe's right of recovery. It demonstrates that Congress considered preemption and chose to preempt state law <u>only</u> to the extent it would "prevent or hinder" the right of recovery provided in section 1621e(a). Courts that have analyzed this preemption provision are in accord. 109

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preemption, where state law actually conflicts with federal law, either because it is impossible for a private party to comply with both state and federal requirements, or because the state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *English v. Gen. Elec. Co.*, 496 U.S. 72, 78–79 (1990) (citation omitted).

¹⁰⁸ See Christensen v. Harris Cty., 529 U.S. 576, 583 (2000) ("We accept the proposition that '[w]hen a statute limits a thing to be done in a particular mode, it includes a negative of any other mode." (quoting Raleigh & Gaston R. Co. v. Reid, 13 Wall. 269, 270 (1872))).

¹⁰⁹ E.g., Strom v. Curtis, No. CV000092123S, 2002 WL 31662356, at *22 (Conn. Super. Ct. Nov. 6, 2002) (analyzing the preemption language of subsection 1621e(c) and choosing to apply state law because state law did not "prevent or hinder" recovery of reimbursement under section 1621e); see also U.S. ex rel. Norton Sound Health Corp. v. Bering Strait Sch. Dist., 138 F.3d 1281, 1283 (9th Cir. 1998) (noting that in subsection 1621e(c) "Congress preempted all provisions of state and local law, and all contract provisions, that would 'prevent or hinder' recovery of reimbursement," and narrowly construing the only limitation on reimbursement under section 1621e (citation omitted)).

Through these two savings clauses Congress expressly left untouched any state law which provides tribes with separate and additional causes of action against tortfeasors, as well as existing causes of action against parties who are liable under other federal statutes such as RICO and the Lanham Act. In short, the text of the statute provides a complete answer to Defendants' preemption argument.

Because Congress directly addressed the intended scope of preemption under section 1621e, the Court need not reach the issue of implied preemption or conflict preemption. Even if it did, "the purpose of Congress is the ultimate touchstone" in implied preemption cases, 111 assessed under the presumption that "Congress does not cavalierly preempt state-law causes of action." *Medtronic*, 518 U.S. at 485. Here, Congress' purpose was to give Tribes and tribal healthcare providers additional tools for recovering damages from tortfeasors and other responsible parties. In light of the savings clauses just reviewed, Congress could not conceivably have intended section 1621e(e)(3) to occupy the field, much less intended to leave "no room for the States to supplement it[]" with state law causes of action like the ones the Nation pleads here. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

Conflict preemption is equally inapplicable, since section 1621e(e)'s text makes plain that state tort law does not "stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *English*, 496 U.S. at 80 (citation omitted), and it is not "impossible for a private party to comply with both state and federal requirements." *Id.* at 79.

¹¹⁰ The Supreme Court has recognized two different types of implied preemption. Field preemption occurs "where the scheme of federal regulation is so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it," while conflict preemption occurs "where 'compliance with both federal and state regulations is a physical impossibility,' 'or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, at 98 (1992) (citations omitted).

¹¹¹ *Id.* (citation and alteration omitted); *see also Medtronic, Inc. v. Lohr*, 518 U.S. 470, 486 (1996) ("Congress' intent, of course, primarily is discerned from the language of the pre-emption statute and the 'statutory framework' surrounding it." (citation omitted)).

Indeed, by referencing "circumstances that establish grounds for liability against the tortfeasor," the IHCIA *incorporates* state tort law and gives tribes an *additional* means by which to enforce existing rights of recovery against tortfeasors. 25 U.S.C. 1621e(e)(3)(A).

Section 1621e's legislative history only confirms this conclusion. When section 1621e was first enacted in 1988,¹¹² the relevant Senate Report explained that the provision was added as a response to the refusal by many insurers to reimburse IHS for care furnished to IHS beneficiaries, because (the insurers argued) the patients themselves were not required to pay for their IHS-furnished care.¹¹³ Subsequent amendments in 1992 "clarifie[d]" that the right of action provided in section 1621e extends to tribes and tribal healthcare providers too.¹¹⁴ The House and Senate reports on the 1992 amendments both describe this change as a clarification of existing law in light of insurers' continued refusal to pay claims, now by tribal organizations operating healthcare programs under the ISDEAA.¹¹⁵ Finally, section 10221 of the Affordable Care Act¹¹⁶ amended section 1621e in 2010 to add a new federal right of action against tortfeasors under subsection (e)(3). The legislative history notes that this amendment was designed to "extend to Tribes and Tribal Organizations the same authority the U.S. has under the Federal Medical Care Recovery Act ("FMCRA") to recover the costs of medical care from a tortfeasor whose action caused an injury or disease to a patient"¹¹⁷

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¹¹² Indian Health Care Amendments of 1988, Pub. L. No. 100-713, § 204, tit. II, 102 Stat. 4784 (1988).

¹¹³ S. Rep. No. 100-508, at 15–16 (1992), as reprinted in 1998 U.S.C.C.A.N. 6183, 6197–98.

¹¹⁴ H.R. Rep. No. 102-643(I), at 45 (1992); see Indian Health Amendments of 1992, Pub. L. No. 102-573, § 209, tit. II, 106 Stat. 4526 (1992).

¹¹⁵ H.R. Rep. No. 102-643(I), at 45–46 (1992); S. Rep. No. 102-392, 20–21 (1992), as reprinted in 1992 U.S.C.C.A.N. 3943, 3962–63.

¹¹⁶ Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 10221(a), tit. X, 124 Stat. 119 (2010).

¹¹⁷ S. Rep. No. 110-197, § 403 (2007). This report relates to S. 1200 (110th Sess.), which contains identical language to S. 1790 (111th Sess.), which was ultimately adopted through section 10221 of the Affordable Care Act, Pub. L. No. 111-148. No independent report exists for S. 1790 (111th Sess.).

At each step of the way, this legislative history demonstrates Congress' studied intent to provide Tribes and tribal organizations with additional and ever more effective tools under federal law to recoup some of the costs of providing care to their citizens. Nothing in this history suggests that Congress intended to preempt, restrict, or replace otherwise available causes of action under state or federal law, and Defendants' contrary hypothesis runs directly afoul of Congress' stated purpose.

Defendants also err in asserting (again, without any support) that Indian tribes had no right of action against tortfeasors prior to the 2010 amendment to section 1621e. Both before and after that amendment, Tribes have routinely availed and continue to avail themselves of state common law remedies, including tort remedies. At least one circuit court has also confirmed that even for causes of action where section 1621e does not create a federal right of action, "nothing in § 1621e precludes a provider from taking advantage of an otherwise applicable" state law regarding tort recoveries. *Blatchford v. Alaska Native Tribal Health Consortium*, 645 F.3d 1089, 1093 (9th Cir. 2011). Thus, even if Tribes and tribal organizations prior to the 2010 IHCIA amendments lacked a federal common law cause of action against tortfeasors for the cost

¹¹⁸ See MB at 21.

¹¹⁹ See, e.g., Quapaw Tribe of Okla. v. Blue Tee Corp., 653 F. Supp. 2d 1166, 1183 (N.D. Okla. 2009) (allowing Tribe's Oklahoma tort law claims against a mining company and a railroad to proceed, over defendants' motion to dismiss); Ponca Tribe of Indians of Oklahoma v. Cont'l Carbon Co., No. CIV-05-445-C, 2008 WL 11338469, at *3 (W.D. Okla. Nov. 21, 2008) (denying some portions of defendants' motion to dismiss Tribe's claims for public nuisance and other torts under Oklahoma law, though concluding that the Tribe did not have standing to assert its members' claims for property damage in that particular context); Red Lake Band of Chippewa Indians v. United States, 936 F.2d 1320, 1325 (D.C. Cir. 1991) (applying state law to tort claims brought by Tribe under Federal Tort Claims Act, which waives the United States' sovereign immunity but relies on state law for the substantive cause of action); cf. Gila River Indian Cmty. v. Henningson, Durham & Richardson, 626 F.2d 708, 715 (9th Cir. 1980) (declining to create a federal common-law cause of action for breach of contract where commercial "agreements between tribes and private citizens" could be "adequately protected by well-developed state contract laws"); Grand Traverse Band of Ottawa & Chippewa Indians v. Blue Cross Blue Shield of Michigan, No. 14-CV-11349, 2017 WL 3116262, at *7 (E.D. Mich. July 21, 2017) (allowing a state-law claim for breach of contract to go forward, over a motion to dismiss, separate and apart from federal claims brought under ERISA). Although these cases do not relate to healthcare costs specifically. Defendants have offered no basis for limiting the type of damages available under state-law causes of action.

of medical care, it would not mean that Tribes also lacked the ability to recover under wholly independent state law causes of action, or under wholly independent federal statutes like RICO and the Lanham Act. 120

MCRA's enactment in the wake of the U.S. Supreme Court's 1947 Standard Oil decision does not suggest otherwise. In Standard Oil, the government asked the Supreme Court to create a new federal common law cause of action; the government was not attempting to pursue claims under state common law. United States v. Standard Oil Co. of Cal., 332 U.S. 301, 316 (1947). The Supreme Court declined the government's invitation, reasoning that the "exercise of judicial power to establish the new liability . . . would be intruding within a field properly within Congress' control." Id. at 316. In effect, then, Standard Oil illustrates the very opposite situation from the one presented here: there, the government was seeking to develop a federal common law cause of action in lieu of an established state law remedy, while here the Nation seeks to pursue those very state law remedies. Congress' subsequent decision in MCRA to create a federal statutory cause of action where no such federal common law right previously existed says nothing about the availability of remedies under other sources of law, including state law.

In the end, section 1621e(e) of the IHCIA provides Tribes with a possible cause of action against tortfeasors, but it has no bearing on the different causes of action asserts here. Since the Nation's claims do not arise under section 1621e(e)(3), they are not limited by that section nor by any individual-patient pleading requirement associated with MCRA as incorporated into that

¹²⁰ Manufacturers' chart of "Grounds For Dismissal" suggests that they believe their argument regarding section 1621e extends to the Nation's RICO and Lanham Act claims (in addition to the Nation's state-law claims), *see* MB at Addendum A, though Manufacturers fail to articulate this argument clearly in their brief. MB at 19–23. As such, they provide <u>no</u> support for the suggestion that the MCRA pleading requirements incorporated into subsection 1621e(e)(3)—which applies only to claims against tortfeasors—have any bearing on non-tort causes of action brought under other sources of law, including other federal statutes.

section. Indeed, any such requirement would frustrate Congress' express command that section 1621e not "be construed to limit any right of recovery available to . . . an Indian tribe, or tribal organization under the provisions of any applicable, Federal, State, or tribal law."

25 U.S.C. § 1621e(k). Accordingly, the Nation need not plead the identities of specific patients in order to recover the expenses its healthcare system incurred and will continue to incur to address the opioid epidemic. Manufacturers' motion to dismiss the Nation's claims for healthcare expenses on this basis must therefore be denied.

B. The Nation's Injuries Are Not Derivative.

Defendants next argue that the Nation's injuries are "derivative of injuries suffered by individuals" who consumed opioids, 122 such that the Nation is precluded from recovering any of these types of damages. This argument also fails.

First, this argument mischaracterizes the nature of the Nation's damages as "indirect" and suggests that the Nation's damages are limited to recovery of healthcare costs. Neither is true. Defendants' misconduct created an increased demand and overabundant supply of opioid products in Oklahoma and nationwide causing the opioid crisis facing the Nation and the rest of the country. That crisis caused the Nation to incur direct costs to address the opioid crisis specifically, and also led to lost revenue and funds. The Nation seeks to recover for the direct

¹²¹ Even if the Nation were seeking to recover under 1621e, Manufacturers are wrong that MCRA's individual-patient pleading requirement would apply. The language referencing MCRA appears only in subsection (e)(3)(A); it is not incorporated into the <u>separate</u> cause of action under subsection (a), which provides a "right to recover from [a] . .third-party tortfeasor, or any other responsible or liable third party." 25 U.S.C. § 1621e(a). Even before the 2010 addition of subsection (e)(3)(A), it had been recognized that tribal health providers had a right to recover tort damages under subsection (a), and the addition of a new, alternative cause of action in subsection (e)(3)(A) did not change that preexisting right. See Alaska Native Tribal Health Consortium v. Settlement Funds Held For or to Be Paid on Behalf of E.R. ex rel. Ridley, 84 P.3d 418, 424 (Alaska 2004). A tribe or tribal healthcare provider can therefore bring a claim under subsection (a) without needing to satisfy any individual-patient pleading requirement that might exist under subsection (e)(3)(A) and MCRA.

¹²² MB at 5–8, 36.

¹²³ Id. at 8 (likening the Nation's claims to those brought against tobacco companies by healthcare providers).

¹²⁴ Am. Compl. ¶¶ 5–6.

injuries it suffered due to Defendants' misconduct, which include not only healthcare costs, but also increased costs to the Nation's criminal justice, social services, welfare, and education systems.¹²⁵ The Nation's direct injuries also include costs for lost productivity¹²⁶ and lower tax revenue caused by Defendants' misconduct.¹²⁷

Second, Defendants ignore the fact that the Nation brings this action in its *parens patriae* capacity. As outlined above, *see* § I, *supra*, the Nation has unquestioned ability to proceed with its claims in a *parens patriae* capacity to protect its quasi-sovereign interests in ensuring the physical and economic health and well-being of its Members. For this reason, the derivative injury rule is inapplicable. The Nation does not seek recovery for injuries to third parties; it seeks direct costs it was required to pay as a result of Defendants' misconduct. The Nation can protect the well-bring of its Members through its *parens patriae* capacity, and doing so does not convert the Nation's claims into subrogation claims on behalf of particular Members.

Courts across the country have rejected Defendants' arguments in other pending opioid-related litigation, allowing government plaintiffs to pursue damages like those alleged by the Nation here. For example, the court in the New York opioid litigation concluded that similar injuries alleged by certain counties in New York were not derivative, but were instead direct injuries that were recoverable. *N.Y. Litig. I*, 2018 WL 3115102, at *24; *N.Y. Litig. II* at 16 (Ex. G). Similarly, in *Everett Litig.*, 2017 WL 4236062, at *7, Purdue argued that the City had not alleged a cognizable injury in part because the City's alleged damages were "derivative of addiction-treatment, addiction-related illnesses, or related injuries" and, as a result, did not constitute injuries to business or property under Washington law. *N.Y. Litig. I*, 2018 WL

¹²⁵ Am. Compl. ¶¶ 22, 294.

¹²⁶ Id.

¹²⁷ *Id.* ¶¶ 263–94.

3115102, at *24; *N.Y. Litig. II* at 16 (Ex. G). Similarly, in *Everett Litig.*, 2017 WL 4236062, at *7. The district court rejected this argument and held that Purdue provided no basis for dismissing the City's claims for lack of cognizable injury and that the City had presented a sufficient basis for all of its claims to proceed based on its pleaded injuries. *N.Y. Litig. I*, 2018 WL 3115102, at *24; *N.Y. Litig. II* at 16 (Ex. G). Similarly, in *Everett Litig.*, 2017 WL 4236062, at *7.

Defendants ignore the surge of opioid cases rejecting their arguments. Instead,

Defendants rely almost exclusively on a string of tobacco-related cases, all of which are

distinguishable. 128 Unlike the plaintiffs in those cases, the Nation does not seek to recoup from

Defendants its medical payments to insureds or for personal injuries suffered by members of the

public. Cf. Perry v. Am Tobacco Co., Inc., 324 F.3d 845, 849 (6th Cir. 2003) (seeking monies

for health insurance plan members required to pay increased health insurance premiums as a

result of other smokers); Int'l Bhd. of Teamsters Local 734 Health & Welfare Trust Fund v.

Phillip Morris, Inc., 34 F. Supp. 2d 626 at 662 (N.D. Ill. 1998) (seeking recovery for damages

from the "individual members' injuries" because labor union suffered no direct injury to itself),

aff'd, 196 F.3d 818 (7th Cir. 1999); Alabama Coushatta Tribe v. Am. Tobacco Co., Order at 2-3,

No. 1:00CV596 (E.D. Tex. Aug. 31, 2001) (ECF No. 50) (seeking recovery "for injuries suffered

by individual members of the Tribe."), aff'd, 46 F. App'x 225 (5th Cir. 2002). In other words,

the Nation's injuries are distinct from those personal injuries of its citizens who are actually

suffering as a result of over-prescription, overuse, and addiction. 129

¹²⁸ MB at 8–10.

¹²⁹ Am. Compl. ¶¶ 16–19.

Instead, the Nation seeks to recover its own governmental costs associated with combatting the opioid epidemic within its tribal territory. 130 As is the case with other plaintiffs in pending opioid litigation, the Nation's injuries are directly traceable to Defendants' misconduct and are in no way derivative of personal injuries suffered by others. See, e.g., N.Y. Litig. II at 11 (Ex. G) ("[T]he plaintiffs here are not simply seeking to recoup medical and drug costs incurred by their employees and Medicaid beneficiaries."); see also Safe Streets Alliance v. Hickenlooper, 859 F.3d 865, 890–91 (10th Cir. 2017) ("The [Plaintiffs] are suing to recover for injuries to their own land, not harms to third parties [I]t is sufficient that the property injuries that the [Plaintiffs] allege are *direct* by-products of the location and manner in which the Marijuana Growers are conducting their operations that purportedly violate the [F]CSA."). Nor does the Nation seek to stand in the shoes of its citizens injured by opioids to recover for their harm. 131 Unlike insurers or third-party payors who may seek to recover indirect losses via the equitable remedy of subrogation, the Nation has no other means of seeking compensation for the pecuniary harms it has suffered (and continues to suffer) as a result of Defendants' misconduct. Simply put, the Nation's damages are its own, and it seeks recovery for its own distinct injuries. Indeed, there is no other, more direct plaintiff who can recover the Nation's damages.

C. The Municipal Cost Recovery Rule Does Not Apply to the Nation.

Defendants also assert that the "municipal cost recovery rule" (also known as the "free public services doctrine") bars the Nation's claims. ¹³² But Oklahoma has not adopted the municipal cost recovery rule, and Defendants cite no Oklahoma authority to support their argument. Nor do Defendants cite a single case from anywhere in the country where the rule has

¹³⁰ *Id.* ¶¶ 22, 294.

¹³¹ Am. Compl. ¶¶ 22, 294.

¹³² MB at 23–25.

been applied against an Indian Tribe. In stark contrast, this Court, as well as other courts addressing analogous circumstances and claims, has rejected the application of the rule in cases where the underlying jurisdiction has not clearly adopted the rule. *See White v. Smith & Wesson*, 97 F. Supp. 2d 816, 822 (N.D. Ohio 2000) ("Defendants argue that this Court should prohibit municipal recovery for all governmental functions, such as police, medical, fire and emergency services, and other related expenditures However, Defendants fail to cite a single case from Ohio that even comes close to advocating such a view."); *see also City of Everett v. Purdue Pharma L.P.*, No. C17-209RSM, 2017 WL 4236062, at *7 (W.D. Wash. Sep. 25, 2017) (denying a motion to dismiss plaintiff's claims to recover costs in connection with the illegal diversion of OxyContin under the municipal cost recovery rule because Purdue "cited no basis under Washington law for dismissing [plaintiff's] claims for lack of cognizable injury").

Even where a state recognizes the rule, courts repeatedly have rejected the use of this rule to escape liability for costs caused by a public nuisance or other long-term and ongoing tortious conduct. See City of Flagstaff v. Atchison, Topeka & Santa Fe Ry. Co., 719 F.2d 322, 324 (9th Cir. 1983) ("Recovery has also been allowed where the acts of a private party create a public nuisance which the government seeks to abate."); Camden Cty. Bd. of Chosen Freeholders v. Beretta U.S.A. Corp., 123 F. Supp. 2d 245, 246 (D.N.J. 2000) ("[E]ven to the extent that New Jersey still embraces the doctrine against recovery of municipal services, this principle does not sweep so broadly as to prevent the County from recovering damages in connection with its public nuisance claims."), aff'd, 273 F.3d 536 (3d Cir. 2001). The New York Supreme Court recently denied a motion to dismiss brought by opioid manufacturers and specifically rejected application of the municipal cost recovery rule. In so doing, the court distinguished expenses

due to accidents and emergencies necessitating the normal provision of public services from public harm incurred due to intentional, persistently deceptive conduct:

Moreover, a review of the current state of the law revealed no case law supporting the manufacturer defendants' contention that such rule bars recovery for municipal expenses incurred, not by reason of an accident or an emergency situation necessitating 'the normal provision of police, fire and emergency services' (City of Flagstaff v. Atchison, Topeka & Santa Fe Ry. Co., 719 F.2d at 324), but to remedy public harm caused by an intentional, persistent course of deceptive conduct. The manufacturer defendants' argument that, despite allegations they designed and implemented materially deceptive marketing campaigns to mislead the public and prescribers about the risks and benefits of prescription opioids, the municipal cost recovery rule forecloses the plaintiffs from recovering the costs for services to treat residents suffering from prescription opioid abuse, addiction or overdose, or for the increased costs of programs implemented to stem prescription opioid-related criminal activities, if accepted, would distort the doctrine beyond recognition.

In re Opioid Litig., No. 400000/2017, 2018 WL 3115102, at *10 (N.Y. Sup. Ct. June 18, 2018) (emphasis added).

Even if the Court were to find that the municipal cost recovery rule was applicable to the Nation's claims, there would be no basis to dismiss the Complaint for a lack of cognizable injury. The Nation's prayer for relief includes multiple categories of damages other than costs of public services, such as statutory damages and penalties, as well as damages related to lost productivity and lower tax revenue, which are clearly not barred by the application of the rule.

For the foregoing reasons, the Court should reject Defendants' argument that the municipal cost recovery rule bars the Nation's claims.

D. The Economic Loss Doctrine Does Not Apply to the Nation's Claims.

Although none of the Defendants directly raise the economic loss doctrine in any of their motions, Generic Manufacturers purport to incorporate by reference the arguments raised by the defendants in the *Summit County* motion to dismiss in Ohio, which included an argument for

¹³³ Am. Compl. ¶ 24, 282.

dismissal under the economic loss doctrine.¹³⁴ However, the *Summit County* motion to dismiss discussed only Ohio law, and the Generic Manufacturers have failed to demonstrate why that doctrine should apply to the Nation's claims under Oklahoma law.¹³⁵ Seeking dismissal in this fashion is improper—the Nation is not obligated to tease out of a brief in another case under another state's law what the Defendants contend is the basis for dismissal here. For that reason alone, Defendants' argument on the economic loss rule should be rejected.

Even if the argument had been properly raised with respect to the Nation's claims (which it was not), the economic loss doctrine would not support dismissal. Under Oklahoma law, the economic loss doctrine prevents tort recovery in certain cases when a party's loss is purely economic and does not entail personal or property damage. *See, e.g., Waggoner v. Town & Country Mobile Homes, Inc.*, 808 P.2d 649, 653 (Okla. 1990). Preventing such recoveries "preserve[s] the remedies" available under contract law. *Dutsch v. Sea Ray Boats, Inc.*, 845 P.2d 187, 193 (Okla. 1992). However, "[t]he economic loss rule has not been applied by the Oklahoma courts other than in a manufacturer's products liability or negligence action for injury to property itself." *Meier v. Chesapeake Operating, L.L.C.*, No. CIV-17-703-F, 2018 WL 3862326, at *7 n.6 (W.D. Okla. Aug. 13, 2018) (collecting cases); *see also Compsource Okla. v. BNY Mellon, N.A.*, 2009 WL 2366112, at *2 (E.D. Okla. July 31, 2009) ("No authority has been cited from a court in Oklahoma specifically adopting the economic loss rule outside of the products liability arena.").

¹³⁴ Joint Motion to Dismiss, at 40–53, ECF 499-1 at 40–53, *County of Summit, Ohio, et al. v. Purdue Pharma L.P.*, Manufacturer Defendants' Joint Motion to Dismiss at 40-53 Case No. 1:18-op-45090 (N.D. Ohio May 25, 2018) (ECF 499-1).

¹³⁵ To be clear, the Nation does not agree with Defendants that the doctrine would bar a sovereign's claims under Ohio law. However, that point is immaterial here.

The Nation does not bring a products liability action and does not assert a negligence action for property damage from a product itself.¹³⁶ There is no contractual relationship between the Nation and Generic Manufacturers, and the tort claims do not interfere with any contract remedies.¹³⁷ Accordingly, the economic loss rule has no application to the present facts. In short, the Nation's claims and allegations fall outside Oklahoma's limited application of the economic law doctrine, and this and Defendants' other arguments on injury must be rejected.

V. THE NATION HAS ADEQUATELY PLED WITH PARTICULARITY.

Defendants argue that (1) the Nation is required to plead all of its claims with particularity, because they all sound in fraud, ¹³⁸ (2) regardless of the pleading standard, the Nation does not allege sufficient facts to state a claim that is plausible on its face, ¹³⁹ and (3) it is insufficient and improper for the Nation to make allegations against Defendants as a group. ¹⁴⁰

As demonstrated below, Defendants' arguments are without merit for three reasons.

First, Defendants ignore that the Nation's nuisance, negligence, and unjust enrichment claims need only satisfy Rule 8(a) (which Defendants do not dispute is satisfied here). Second, for those claims subject to Rule 9(b), Defendants dramatically overstate the degree of particularity required and demand recitation of minute details, even though the Nation's Complaint gives plentiful details that are beyond sufficient to put Defendants on notice of the claims brought against them. The level of particularity Defendants argue for is simply not required and would be impossible to provide—and would effectively bar claims involving any but the simplest fraud. Third, group pleading objections are context specific and applied in factually distinguishable

 $^{^{136}}$ See generally Am. Compl. ¶¶ 353–493.

¹³⁷ See generally id. ¶¶ 419–493.

¹³⁸ DB at 25–26; GB at 8–9; MB at 49–58.

¹³⁹ PB at 3–4; GB at 8–9; MB at 50–55.

¹⁴⁰ PB at 1–2, 4; GB at 11; MB at 54.

cases, but in any event, Defendants are still well-apprised of the specific allegations and claims brought against them individually.

A. Rule 9(b) is Designed to Give Defendants Notice of the Claims Against Them, Not Painstaking Details of All Possible Facts.

In general, Rule 9(b) of the Federal Rules of Civil Procedure requires a plaintiff alleging fraud to "state with particularity the circumstances constituting fraud[.]" Fed. R. Civ. P. 9(b). However, "Rule 9(b) does not require omniscience; rather the Rule requires that the circumstances of the fraud be pled with enough specificity to put defendants on notice as to the nature of the claim." Williams v. Duke Energy Int'l, Inc., 681 F.3d 788, 803 (6th Cir. 2012) (citation omitted). Indeed, the purpose of Rule 9(b) is just to provide "fair notice of the substance of a plaintiff's claim in order that the defendant may prepare a responsive pleading." Michaels Bldg. Co. v. Ameritrust Co., N.A., 848 F.2d 674, 679 (6th Cir. 1988). Thus, "[s]o long as a [plaintiff] pleads sufficient detail—in terms of time, place and content, the nature of a defendant's fraudulent scheme, and the injury resulting from the fraud—to allow the defendant to prepare a responsive pleading, the requirements of Rule 9(b) will generally be met." United States ex rel. SNAPP, Inc. v. Ford Motor Co., 532 F.3d 496, 504 (6th Cir. 2008). For all other claims, the notice-pleading standard under Federal Rule of Civil Procedure 8(a)(2) governs, which requires only "a short and plain statement of the claim showing that the pleader is entitled to relief." See Fed. R. Civ. P. 8(a)(2).

As an initial matter, Defendants seek to alter this established standard by attempting to recast the well-pled nuisance, negligence, and unjust enrichment claims into causes of action that "sound in fraud." A claim "sounds in fraud," however, only if the plaintiff "allege[s] a unified course of fraudulent conduct and rel[ies] entirely on that course of conduct as the basis of a claim." *In re Daou Sys., Inc.*, 411 F.3d 1006, 1027 (9th Cir. 2005) (quoting *Vess v. Ciba-Geigy*

Corp. USA, 317 F.3d 1097, 1103 (9th Cir. 2003)). By contrast, "[i]n a case where"—as here—
"fraud is not an essential element of a claim, only allegations of fraudulent conduct must satisfy the heightened pleading requirements of Rule 9(b)." Id. (quoting Vess, 317 F.3d at 1105).

"Allegations of non-fraudulent conduct need satisfy only the ordinary notice pleading standards of Rule 8(a)." Id. (quoting Vess, 317 F.3d at 1105); see also Lone Star Ladies Inv. Club v.

Schlotzsky's Inc., 238 F.3d 363, 368 (5th Cir. 2001) ("Where averments of fraud are made in a claim in which fraud is not an element, an inadequate averment of fraud does not mean that no claim has been stated."). Thus, the Nation's claims for nuisance, negligence, and unjust enrichment need only satisfy Rule 8. Defendants do not dispute that Rule 8 is met for these claims (and nor could they). For this reason, the Court should reject Defendants' particularity arguments for these non-fraud claims.

Regarding the Nation's claims that sound in fraud, in ruling upon a motion to dismiss under Rule 9(b), a court must read the allegations in harmony with Rule 8's "policy of simplicity in pleading" which calls for "simple, concise, and direct" allegations. *Michaels Bldg.*, 848 F.2d at 679 (citation omitted). Courts should not be "too exacting" or "demand clairvoyance from pleaders" in determining whether Rule 9(b) is satisfied. *Id.* at 681; *Ford v. Penn. Higher Educ.*Assistance Agency, No. 5:17-cv-49, 2018 WL 1377858, at *5 (N.D. Ohio Mar. 19, 2018). "[I]f the defendant has fair notice of the charges against [it], [Rule 9(b)] is satisfied." *Ford*, 2018 WL 1377858, at *4 (quoting *Shapiro v. Merill Lynch & Co.*, 634 F. Supp. 587, 594 (S.D. Ohio 1986); see also Williams, 681 F.3d at 803.

As outlined below, the Nation's allegations here exceed Rule 9(b)'s requirements for these claims that sound in fraud. 141

¹⁴¹ As explained below, *see* § VIII.F, *infra*, the Nation's Lanham Act claim is not subject to Rule 9(b)'s heightened pleading requirement.

B. The Nation's Allegations Give Defendants the Necessary Notice.

For those claims that sound in fraud and are actually subject to Rule 9(b), the particularity requirement is easily satisfied by the Nation's detailed, 141-page Complaint. Indeed, the controlling cases demand only particularity, not a recitation of all minute details. Moreover, where a complaint alleges "a complex and far-reaching fraudulent scheme," pleading every instance of fraud "would be extremely ungainly, if not impossible." *United States ex rel. Bledsoe v. Cmty. Health Sys., Inc.*, 501 F.3d 493, 509–10 (6th Cir. 2007) (quotation omitted). Here, the Nation alleges a series of sophisticated, complex, and ongoing fraudulent schemes on the part of all Defendants, designed to create a captive market of opioid-addicted individuals and unlawfully profit from opioid sales, and then open the distribution floodgates to profit from opioid diversion. As further described below, the Complaint provides details with respect to the fraud committed by all Defendants.

Despite these details, Defendants still ask this Court to dismiss the allegations for lack of particularity. Defendants argue that greater specifics regarding the fraud are required, including who heard and relied upon the misrepresentations. Not only is the particularity standard Defendants call for not required, *see* § V, *infra*, but even if it was, it would be impracticable to meet and would effectively bar all but the simplest fraud claims. And it would certainly bar fraud claims for complex, multi-decade, nationwide, industry-wide, fraudulent schemes—such as the scheme at issue here.

It should come as no surprise that courts in eleven other opioid cases have found that similarly situated plaintiffs satisfied the particularity requirement when reviewing similar

allegations in light of objections by the defendants, some of whom are also Defendants here. 142

This Court should reach the same conclusion.

The Nation provides multiple examples of specific misrepresentations attributed to each Marketing Defendant, including through their Front Groups¹⁴³ that appeared to be independent and their KOLs that were secretly paid by Marketing Defendants to promote their pro-opioid message. 144 The Nation identifies detailed and specific examples of how Marketing Defendants misrepresented and disseminated false and misleading information about and otherwise misrepresented the risks and benefits of opioids to mislead doctors and the general public and dramatically increase the demand for opioids and the number of prescriptions written for them, including: (i) quotes taken directly from source material regarding opioids and their use; 145 (ii) the manner in which those misrepresentations were disseminated to doctors and the medical community through Front Groups, KOLs, continuing medical education programs, and speaker programs; 146 (iii) name-brand and generic advertising to promote their products directly to doctors and consumers; 147 and (iv) funding, editing, and distributing publications that supported their misrepresentations. 148 In addition, the Nation specifically alleges how generic-equivalent products were encompassed within these false marketing efforts, how the Generic Manufacturers failed to correct misstatements and misrepresentations by Brand-Name Manufacturers while

¹⁴² Okla. Litig. at 1 (Ex. C); N.H. Litig. at 10–11 (Ex. D); Ohio Litig. at 10 (Ex. C), Alaska Litig. at 15–16 (Ex. F), N.Y. Litig. I, 2018 WL 3115102, at *23; N.Y. Litig. II at 4 (Ex. G), Tenn. Litig., 2018 WL 3349093, at *3, Mo. Litig. at 3 (Ex. I), Chicago Litig., 211 F. Supp. 3d at 1066; W. Va. Litig. I at 6 (Ex. J), W. Va. Litig. II at 3 (Ex. K).

¹⁴³ All capitalized terms are defined in the Complaint unless otherwise noted" or something to that effect.

¹⁴⁴ See, e.g., Am. Compl. ¶ 104.

¹⁴⁵ *Id.* ¶¶ 105–115.

¹⁴⁶ *Id*.

 $^{^{147}}$ Id. ¶¶ 104–15, 117, 122, 142.

¹⁴⁸ *Id.* ¶¶ 104–5, 127–33, 312, 316, 359–61.

benefiting from them, and how Generic Manufacturers failed to communicate warnings to physicians and patients.¹⁴⁹ These details go well beyond the specificity required by Rule 9(b).

The Nation further explains how Diversion Defendants were bound by the FCSA and other laws but deliberately disregarded their legal obligations to monitor and report suspicious activity and red flags, ignored the blatant criminal diversion of opioids, ignored their own procedures for identifying and reporting diversion, 150 and engaged in fraud by refusing to report and halt suspicious orders, which increased the rate of prescriptions and dramatically increased their overall profits. 151 As the Nation alleges, these acts and omissions permitted widespread diversion of opioids, and caused (and are causing) profound and direct harm to the Nation. These allegations are more than sufficient to satisfy Rule 9(b) as a scheme to defraud by omission. In re Whirlpool Corp. Front-Loading Washer Prod's. Liab. Litig, 684 F. Supp. 2d 942, 961 (N.D. Ohio 2009) ("Rule 9(b) does not require fraud-by-omission claims to 'specify the time, place, and specific content of an omissions as precisely as would a . . . false representation claim." (citation omitted)).

In their moving brief, Marketing Defendants improperly argue that the Nation must identify each and every doctor who heard a false statement and prescribed an opioid because of that false statement. 152 They also argue that the Nation must identify the specific individuals whose medical costs they incurred and seek to recover.¹⁵³ This is plainly an impossible task in this case, which of course is the point. Not surprisingly, Defendants fail to provide any authority that such minute details are required in this case or any other case involving such a complex,

 $^{^{149}}$ Id. ¶¶ 157–61. 150 Id. ¶¶ 230–36.

¹⁵¹ *Id*. ¶¶ 212–23, 232–234.

¹⁵² MB at 50.

¹⁵³ *Id*. at 22.

massive, multi-decade, multi-defendant, multi-dimensional, fraudulent scheme. ¹⁵⁴ Moreover, Marketing Defendants' argument essentially turns on what influenced physicians' and specific prescribers' states of mind. But Rule 9(b) provides that "conditions of [] mind"—including knowledge and intent—"may be alleged generally," 155 as the Nation did here. In any event, it is obvious that the intended result of Marketing Defendants' massive scheme was to cause physicians to be misled into changing their prescribing habits; otherwise, Defendants' fraudulent actions would be pointless. See, e.g., United States ex rel. Brown v. Celegene Corp., No. CV 10-3165, 2014 WL 3605896, at *8 (C.D. Cal. 2014) ("It is implausible that a fraudulent scheme of the scope of that alleged [by the plaintiff] would be entirely feckless."). In short, the Nation need not connect a particular doctor to a particular misrepresentation.

At this stage of the litigation, the Nation's well-pled allegations are at least sufficient to put Defendants on notice of the nature of the claims against them. Williams, 681 F.3d at 803. For all of these reasons, the Court should deny Defendants' motions to dismiss for failure to satisfy the particularity requirement of Rule 9(b).

¹⁵⁴ Unlike those cases cited by the Marketing Defendants, the Nation does not seek to recover sums previously paid for medically unnecessary prescriptions due to doctors prescribing opioids based on Marketing Defendants' misrepresentations. Cf. City of Chicago v. Purdue Pharma L.P., No. 14 C 4361, 2015 WL 2208423, at *13-14 (N.D. Ill. May 8, 2015) (seeking reimbursement for false claims paid by plaintiff that were medically unnecessary and ineligible for payment due to defendants' misconduct); Travelers Indem. Co. v. Cephalon, Inc., 620 F. App'x 82, 86 (3d Cir. 2015) (seeking recovery of sums paid by insurer's claimants for drugs that were marketed off-label); Snapp, 532 F.3d at 506 (seeking recovery because defendant fraudulently induced government to make payments under government contract).

The Phillip Morris case cited by Manufacturer Defendants is inapplicable and easily distinguishable because the Nation does not seek to recover amounts on behalf of its injured citizens. Cf. United States v. Phillip Morris, Inc., 153 F. Supp. 2d 32, (D.D.C. 2001) (government seeking money on behalf of the injured persons for whom it brought suit). As outlined herein, the Nation seeks to recover its own direct damages, not those suffered by members of the public. See §§ I, IV, supra.

¹⁵⁵ Fed. R. Civ. P. 9(b).

C. Defendants' Objections to "Group Pleading" Lack Merit.

Marketing Defendants and Pharmacies also argue that Rule 9(b) does not permit "group pleading," ¹⁵⁶ and the Nation improperly lumped all Defendants together, without distinguishing which Defendant made what misrepresentation or omission. This argument is without merit. The relevant question is whether the Defendants have been adequately put on notice of the basis for the claims against them. *Id.* Inarguably, they have. Courts in other opiod cases have rejected Defendants' similar "group pleading" objections. ¹⁵⁷ This Court should do the same here.

There is no hard-and-fast rule against "group pleading." As in any Rule 9(b) analysis, the ultimate question is whether the allegations give the defendants adequate notice of the allegations against them. *See, e.g., In re Duramax Diesel Litig.*, 298 F. Supp. 3d 1037, 1056–57 (E.D. Mich. 2018) ("Plaintiffs have adequately alleged the prima facie elements of a RICO claim with sufficient specificity to put Defendants on notice of their alleged involvement in the enterprise. . . . Although the precise identity of the subsidiary and/or employee which may have taken certain actions is unclear, that level of detail is unnecessary to put the Bosch Defendants on notice of the claims made against them.").

As an initial matter, the prohibition on group pleading generally arises in the securities context under a factually distinguishable scenario in which a plaintiff attempts to hold corporate officers vicariously liable for the statements of their corporations. The cases cited by Defendants, such as *Hoover v. Langston Equipment Assocs., Inc.*, involve relatively small numbers of defendants who are charged with making a relatively small number of misrepresentations, and situations in which the allegations did not support the inference of one

¹⁵⁶ MB at 54; GB at 11; PB at 4.

¹⁵⁷ See, e.g., Ohio Litig. at 4 (Ex. E); Mo. Litig. at 2-3 (Ex. I).

defendant's responsibility for the misrepresentation of another.¹⁵⁸ 958 F.2d 742, at 744–45. In each case, the plaintiff's allegations against "all defendants" did "not enable a particular defendant to determine with what it [was] charged." *See, e.g., id.* at 744–45; *see also Kurek v. Ohio Dep't of Dev. Disabilities*, No. 3:16CV623, 2017 WL 1555930, at *6 (N.D. Ohio Jan. 20, 2017) (stating that "[plaintiff's] shotgun assertions leave each defendant incapable of knowing what plaintiff claims he or she did that violated the Constitution").

The opposite is true here. The Nation more than adequately puts Defendants on notice of the claims in this litigation. It asserts that Manufacturers have engaged, and continue to engage, in a massive marketing campaign that misstates and conceals the risks of treating chronic pain with opioids, spurred and continues to drive an enormous demand for prescription opioids for non-medical purposes, ¹⁵⁹ enabled manufacturers to overcome the longstanding medical consensus that opioids are highly addictive and, therefore, unsafe for the treatment of chronic pain, resulted in a staggering number of opioid users beyond those with legitimate medical needs, leading to alarming rates of addiction. ¹⁶⁰ It also asserts that Diversion Defendants disregarded their legal obligations in order to profit from the sale of opioids that they knew or should have known were being diverted to illegitimate channels of distribution and sale. ¹⁶¹

VI. STATUTES OF LIMITATIONS ARE NOT A BAR TO RECOVERY.

Marketing Defendants contend that the Nation's claims are time-barred. This argument fails for three primary reasons: (1) statutes of limitation do not apply to tribal governments; (2) the statutes of limitation arguments are not in any event appropriate for

¹⁵⁸ Similarly, *Cataldo v. United States Steel Corp.*, 676 F.3d 542 (6th Cir. 2012) involved a breach of ERISA fiduciary duty against sixteen defendants, including the plaintiffs' employer, their union, and their plan administrator.

¹⁵⁹ See, e.g., Am. Compl. ¶ 98.

¹⁶⁰ See id. ¶¶ 5−6.

¹⁶¹ *See, e.g., id.* ¶ 14.

¹⁶² MB at 58–66.

resolution at the motion to dismiss stage; and (3) the Nation's allegations support both the delayed accrual of its claims and the tolling of the limitation periods because of Defendants' fraudulent concealment and continuing tortious conduct.

A. Statutes of Limitation Do Not Apply to Suits Brought by Tribal Governments.

In general, Oklahoma law provides that "statutes of limitation shall not bar suit by any government entity acting in its sovereign capacity to vindicate public rights, and that public policy requires that every reasonable presumption favor government immunity from such limitation." *Okla. City Mun. Improvement Auth. v. HTB, Inc.*, 769 P.2d 131, 134 (Okla. 1989); see also Town of Cyril v. Mobil Oil Corp., 11 F.3d 996, 998 (10th Cir. 1993) (sovereign "is entitled to avoid the bar of the statute of limitation if it sues in its 'sovereign capacity' in an appropriate case" (citing *HTB, Inc.*, 769 P.2d at 133)).

Tribal governments are no different. Similar to how state governments are immune from statutes of limitations, so too are tribal governments (which are also government entities acting in their sovereign capacity). Indeed, the United States Supreme Court has recognized that tribes retain "inherent powers of a limited sovereignty which ha[ve] never been extinguished." *United States v. Wheeler*, 435 U.S. 313, 322 (1978) (internal citation omitted). Moreover, the Supreme Court already has declined to apply state statutes of limitation in the context of Native-American land claims. *See, e.g., Oneida County v. Oneida Indian Nation of N.Y.*, 470 U.S. 226, 241 (1985) (explaining that there is a federal policy "against the application of state statutes of limitations in the context of Indian land claims").

At least one court has explicitly held that tribal government claims are not subject to statutes of limitation. *See Pequot Pharm. Network v. Conn. Hospice, Inc.*, 6 Mash. Rep. 323, 333 (Mashantucket Pequot Tribal Ct. 2015). In that case, the court held that "[f]or the same

reason immunity from suit is inherent in the Mashantucket Pequot Tribal Nation's status as domestic dependent sovereign, immunity from the statute of limitations is also an inherent core aspect of the Mashantucket Pequot Tribal Nation's sovereign authority." *Id.* The court based its holding on the Tribe's common law privilege of *nullum tempus occurit regi* (i.e., time does not run against the king). *Id.* at 327. Under Oklahoma law, the doctrine of *nullum tempus* protects claims that might otherwise be barred where the sovereign seeks to vindicate a public right. *See HTB*, 769 P.2d at 133 (citing *Foote v. Town of Watonga*, 130 P. 597, 598 (Okla. 1913)); *see also Okla. ex rel. Cartwright v. Tidmore*, 674 P. 2d 14, 16 (Okla. 1983) (defining a public right is one which "affect[s] the public generally[,]" as opposed to a class of individuals).

Here, the claims asserted by the Nation allege injury to the tribe as a whole for the harms they have suffered as a result of the opioid crisis. The rights implicated concern the Nation Members generally and are therefore clearly public. Thus, for the same reasons that tribal governments and states both enjoy sovereign immunity, tribal governments are also exempt from statutes of limitation—just as other states and sovereigns. *See also Pequot*, 6 Mash. Rep. at 332 ("[N]ullum tempus and sovereign immunity may be viewed as opposite sides of the same coin." (quoting *State v. Lombardo Bros. Mason Contractors, Inc.*, 54 A.3d 1005 (Conn. 2012))). Marketing Defendants' argument should be rejected on this basis alone.

B. Adjudication of Statutes of Limitation is Premature.

Even if statutes of limitation apply to tribal governments, the arguments are not appropriate for resolution at this stage of the litigation. Statute of limitations generally are not a defense that are properly applied on a motion to dismiss. *See, e.g., Lutz v. Chesapeake*Appalachia, L.L.C., 717 F.3d 459, 464 (6th Cir. 2013) ("[A] motion under Rule 12(b)(6), which considers only the allegations in the complaint, is an 'inappropriate vehicle' for dismissing a claim based upon a statute of limitations." (citation omitted)). Accordingly, the Sixth Circuit has

long held that dismissal of a complaint on such grounds is proper only "when the statement of the claim affirmatively shows that the plaintiff can prove no sets of facts that would entitle him to relief." *Duncan v. Leeds*, 742 F.2d 989, 991 (6th Cir. 1984) (citation omitted). The burden of proof lies with the defendant to prove that is the case. *See, e.g., Lutz*, 717 F.3d at 464. This is a particularly demanding standard, as "[t]he complaint must be liberally construed" in favor of the plaintiff "in determining whether the complaint is time-barred." *Duncan*, 742 F.2d at 991 (citation omitted).

Here, Marketing Defendants' arguments simply do not meet this high standard.

Defendants make no attempt to illustrate precisely how the Nation's claims are facially timebarred; they just say that is the case. 163 But such conclusory statements do not affirmatively show that the Nation can prove no set of facts entitling to relief. Moreover, this is not a simple personal injury case with elementary facts—but instead a case about a well-funded, well-designed, and well-executed scheme to unlawfully market and illegally distribute addictive opioids throughout the country over several decades, causing the Nation to suffer injury. What the Nation knew and when it knew it is a factual dispute requiring extensive discovery, and cannot be easily resolved upon a motion to dismiss. Simply put, Defendants' arguments are entirely premature and are not appropriate for consideration at this time.

C. The Nation Has Adequately Pled Facts to Toll and Delay Accrual of All Applicable Statutes.

Even if statutes of limitation apply to tribal governments, and even if the Court decides to address the arguments at this stage of the litigation, the Nation's claims are nonetheless timely.

Marketing Defendants assert that the Nation's claims are time-barred pursuant to a two- or four-

¹⁶³ See e.g., MB at 58–59.

year statute of limitations, depending on the specific claim considered.¹⁶⁴ They argue that, because the Complaint was filed on April 3, 2018, the Nation "with the exercise of reasonable diligence, should have known of their claims at least four years before" the filing date and the suit should be dismissed.¹⁶⁵ This argument is without merit because any applicable statute is tolled and the Nation's Complaint adequately pleads facts to establish the tolling of all applicable statutes.

1. The Nation's Claims Did Not Accrue Until the Nation Discovered That It Was Injured Due to Defendants' Misconduct.

In general, the statute of limitations runs forward "after the cause of action [has] accrued," 12 Okla. St. § 95(A), not backward from the filing of the complaint. And a cause of action does not accrue, and the statute of limitations does not begin to run, until injury to a potential plaintiff becomes certain rather than speculative. *Marshall v. Fenton, Fenton, Smith, Reneau & Moon, P.C.*, 899 P.2d 621, 623 (Okla. 1995). More specifically, a cause of action accrues only "when a litigant could first maintain an action to successful conclusion." *Ranier v. Stuart & Freida, P.C.*, 887 P.2d 339, 340–41 (Okla. Civ. App. 1994). In other words, accrual requires that each element of the claim be satisfied. *Wing v. Lorton*, 261 P.3d 1122, 1125 (Okla. 2011) (citations omitted). Often, injury is the final element to be satisfied, and Oklahoma courts have consistently recognized that a negligence claim "accrues when any injury to the plaintiff, for which an action could proceed, is certain and not merely speculative." *Marshall*, 899 P.2d at 623 (citation omitted).

Even if a claim is deemed to have accrued, the delayed "discovery rule may delay the start of the statute of limitations." *Horton v. Hamilton*, 345 P.3d 357, 360 (Okla. 2015). Under

¹⁶⁴ MB at 58.

¹⁶⁵ *Id*.

the delayed discovery rule, the statute of limitations will not begin to run "until the injured party knows or, in the exercise of reasonable diligence, should have known of the injury." See, e.g., Digital Design Grp., Inc. v. Info Builders, Inc., 24 P. 3d 834, 841 (Okla. 2001). The "purpose of the rule is to exclude the period of time during which the injured party is reasonably unaware that an injury has been sustained " Id. at 841 (quotation omitted). The Oklahoma Supreme Court "has allowed the use of the discovery rule in a variety [of] cases—all of which involved situations in which the injury was concealed from the plaintiff or the injury was unlikely to come to the attention of the injured party." *Id.* at 840–41. This is often the case for fraud claims, which accrue "when in the exercise of reasonable diligence, [the fraud] could have been discovered." Brown v. W.M. Acree Trust, 999 P.2d 1119, 1121 (Okla. Civ. App. 2000) (citing Harjo's Heirs v. Standley, 305 P. 2d 864, 867 (Okla. 1956)). Still, "[t]he means of discovering the fraud must be in the hands of the party being defrauded and the defrauding party must not have covered up his fraud to the extent it would be difficult or impossible to discover." *Id.* (citing Gearhart Indus. v. Grayfox Operating Co., 829 P.2d 1005, 1006–07 (Okla. Civ. App. 1992)).

The Nation's claims here did not accrue, and the statutes of limitations did not begin to run, until the Nation discovered that it had been injured by Defendants' misconduct. At this time, the Nation still does not believe its claims have accrued because it still has not discovered the true extent and nature of Defendants' wrongful conduct and the Nation's injuries. Nor was the Nation on notice of its claims due to prior lawsuits filed by other, unrelated third parties. The simple fact that the City of Chicago or a county in California filed a complaint does not prove that the Nation knew about that filing, or even that the Nation knew of injuries occurring in its

own community. But in any event, reference to these prior lawsuits is wholly inappropriate on a motion to dismiss. 166

Even if the Nation's claims accrued at an earlier date (which they did not), there can be no doubt that the Nation sufficiently alleged facts supporting application of the delayed discovery rule in this case. As further discussed below, *see* § VI.3.b, *infra*, Defendants went to exceptional lengths to conceal their misdeeds.

To dispute timeliness, Marketing Defendants latch onto the dates of Defendants' misrepresentations, improperly arguing that the limitations period immediately began at the time when each of the misrepresentations alleged in the Complaint were first made. 167 Under Marketing Defendants' theory, the Nation should have known it was experiencing certain harm by any the alleged misstatements regarding the addictive nature of opioids used for pain management as early as 1995. 168 But the Nation's injuries did not occur immediately upon each misrepresentation. Instead, the injuries occurred many years later—after the misrepresentations made their impact and caused the market demand for opioids to surge throughout the country. In essence, Defendants argue that the Nation should have predicted its future damages decades in advance, and failure to do so now renders its claims untimely.

¹⁶⁶ Courts nationwide have found that "earlier filed lawsuits do not constitute a sufficient bases at the Rule 12(b)(6) stage to conclude as a matter of law that the limitations period was triggered or before a date certain." *E.g.*, *W. & S. Life Ins. Co. v. JPMorgan Chase Bank, N.A.*, 54 F. Supp. 3d 888, 903 (S.D. Ohio 2014) (collecting cases). Moreover, reference to those cases goes beyond the Nation's Complaint and may not be considered on a motion to dismiss. *E.g.*, *Kostrzewa v. City of Troy*, 247 F.3d 633, 643 (6th Cir. 2001) ("The district court, in reviewing a motion to dismiss, may not consider matters beyond the complaint."). In any event, the two unrelated cases cited by the Marketing Defendants are fundamentally different at their core—including different plaintiffs, different parts of the county, different substantive law, and different types of relief sought. For example, the *City of Chicago* case sought reimbursement for false claims paid by the City that were medically unnecessary and ineligible for payment due to defendants' misconduct. *See Chicago Litig.*, 2011 F. Supp. at 1063. Despite these critical differences, Marketing Defendants fail to explain how the Nation should have discovered or was on notice of its own, separate injuries caused by Defendants.

¹⁶⁸ See id., Addendum B, at 77 (listing Nation's alleged misrepresentations and their location within the First Amended Complaint); see also, id. at 62.

Marketing Defendants also argue that the Nation's claims accrued many years ago due to certain public documents and prior lawsuits. However, Defendants fail to cite to any applicable authority that either category of information was sufficient to put the Nation on notice of its claims, and those few cases cited by Defendants are easily distinguishable. 170

Regarding the public documents, Marketing Defendants appear to argue that the Nation's claims began to accrue immediately after the scientific community and others first questioned Marketing Defendants' misleading statements. Marketing Defendants argue that their alleged role in causing the opioid crisis was self-evident by way of the public documents themselves, and that the Nation was legally obligated to file its claims immediately when those public documents were released. In other words, that the fines and settlements Defendants paid is evidence that the Nation was on notice of its causes of action years earlier. But once again, a cause of action does not accrue under Oklahoma law until a plaintiff's injury becomes "certain, not merely speculative," *Marshall*, 899 P.2d at 623, and the injured party knows or, in the exercise of reasonable diligence, should have known of the injury, *Digital Design Grp.*, *Inc.*, 24 P. 3d at 841. Moreover, Defendants ignore their own extensive efforts to cover up and avoid disclosing the

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¹⁶⁹ The Nation asks that this Court exclude Manufacturer Defendants' reference to prior lawsuits filed by the City of Chicago and the California counties, as such goes beyond the Complaint and may not be considered on a motion to dismiss. *See, e.g., Kostrzewa v. City of Troy*, 247 F.3d 633, 643 (6th Cir. 2001) ("The district court, in reviewing a motion to dismiss, may not consider matters beyond the complaint.").

¹⁷⁰ The three cases cited by Defendants are entirely dissimilar to the Nation's claims. First, no prior suit was filed on the Nation's behalf for *its* injuries. *Cf. Reaves v. Cable One, Inc.*, No. 11-cv-03859, 2015 WL 12747944, at *4 (N.D. Ala. Mar. 16, 2015) (holding that plaintiff's class action complaint was time-barred because plaintiff was previously a member of the putative class in an identical class action complaint brought years earlier). Second, the Nation is neither a new plaintiff to a prior suit nor otherwise joining claims previously asserted by another plaintiff. *Cf In re Wells Fargo Mortgage-Backed Certificates Litig.*, 2010 U.S. Dist. LEXIS 124498, at *12–13, *36-37 (N.D. Cal. Oct. 19, 2010) (holding that new plaintiffs to complaint was time-barred because of previous complaints filed in same action). Third, the Nation does not seek to add a new defendant to claims it discovered many years earlier. *Cf. Thieltges v. Royal Alliance Assocs.*, *Inc.*, 334 P.3d 382, 386 (Mont. 2014) (holding plaintiff's claims against newly added defendant were time-barred because plaintiff could have discovered its claims against that defendant when plaintiff originally discovered its claims against other related defendants also involved in single transaction).

¹⁷¹ MB at 63 (discussing the Nation's mention of FDA warnings given that in 2013 opioids presented serious risks and a high potential for abuse).

¹⁷² *Id.* at 64.

full extent of their fraud. As discussed below, this concealment alone prevented the Nation's claims from accruing based on any publicly available information. Simply put, Marketing Defendants cannot escape application of the discovery rule by simple reference to what they describe as public information available in the Nation's Complaint.

In any event, what the Nation knew or when it should have known about the facts that gave rise to its claims are issues that must be explored through discovery and decided by a jury. They are not appropriate for a Rule 12(b)(6) dismissal.

2. Marketing Defendants' Fraudulent Concealment Tolls the Statute of Limitations.

The Nation has also pled facts establishing that Marketing Defendants are equitably estopped from asserting a statute of limitations defense because they intentionally concealed their unlawful conduct and defrauded the public.

Under Oklahoma law, fraudulent concealment is defined as:

[A]n implied exception to the statute of limitations, and a party who wrongfully conceals material facts, and thereby prevents a discovery of his wrong, or the fact that a cause of action has accrued against him, is not allowed to take advantage of his own wrong by pleading the statute, the purpose of which is to prevent wrong and fraud.

Kan. City Life Ins. Co. v. Nipper, 51 P.2d 741, 747 (Okla. 1935) (citation omitted). For the doctrine to apply, there must be "some actual artifice to prevent knowledge of the facts; some affirmative act of concealment or some misrepresentation to exclude suspicion and prevent inquiry." Id. (citation omitted); see Clulow v. State of Oklahoma, 700 F.2d 1291, 1301 (10th Cir. 1983) (to toll the statute of limitations, a defendant "must show a concealment of facts that would prevent him from knowing that he had a cause of action").

The Nation has alleged facts that warrant application of the fraudulent concealment doctrine. In particular, Marketing Defendants affirmatively deprived the Nation of actual or

Implied knowledge of the facts sufficient to put it on notice of potential claims. Marketing Defendants' entire course of action giving rise to this case has served to thwart the discovery of opioids' addictive nature. The Nation clearly alleges that Marketing Defendants have "engaged in a multi-million dollar marketing campaign to minimize and misstate the risks of addiction and abuse when prescription opioids are used to treat chronic pain." This campaign has consisted of "websites, promotional materials, conferences, [prescribing] guidelines for doctors, and other vehicles . . . suggest[ing] that the risk of addiction when opioids are used for chronic pain [is] low—statements directly contrary to established scientific evidence." Those other vehicles included Front Groups and KOLs, organizations and established professionals, who were paid by Marketing Defendants to disseminate misleading information regarding the safety of prescribing and taking opioids. 175

Marketing Defendants' campaign of misdirection and minimization concealed from and prevented the Nation, and communities across the country, from discovering the nature and source of the injury they had suffered until only recently, and indeed even now the full scope of Defendants' scheme and the resulting injury is not known. Indeed, the Nation could not have known they had even been harmed by a third party until the veracity of Marketing Defendants' misleading statements had been impugned by those with the knowledge and authority to do so, and until that information had been widely disseminated. One such instance occurred only as recently as August of 2016, when the Surgeon General of the United States "expressed concern that 'heavy marketing to doctors' had led many to be 'taught—incorrectly—that opioids are not

¹⁷³ Am. Compl. ¶ 102.

 $^{^{174}}$ Id. ¶ 103.

¹⁷⁵ *Id.* ¶¶ 104–05.

 $^{^{176}}$ *Id.* ¶ 300.

addictive when prescribed for legitimate pain[.]""¹⁷⁷ The flood of addictive prescription drugs on the market, coupled with misleading statements concerning their danger, directly caused the opioid crisis the Nation is combatting today. All the while, Defendants hid their role from the Nation and other sovereigns that were injured.¹⁷⁸ Indeed, the full scope of Defendants' perfidy is not known even to this day.

As another example, the Nation alleges that, as early as 1996, at least one of the Marketing Defendants represented the danger of addiction to opioids in patients taking them for pain as "very rare." Ten years later, those same Marketing Defendants settled a claim for nearly a billion dollars and admitted that certain employees had misstated the addictive dangers of OxyContin, one of its most powerful opioids. In the interim, Marketing Defendants enlisted KOLs and established Front Groups, such as the American Pain Foundation, to spread its pro-opioid message. All of these steps, which present merely the broadest snapshot of Marketing Defendants' activities, were designed to conceal the true danger of opioid use and as such, were misrepresentations meant "to exclude suspicion and prevent inquiry." *Kan. City Life Ins. Co.*, 51 P.2d at 747. In short, these misrepresentations operate to toll the statute of limitations under a theory of fraudulent concealment, and discovery is appropriate on this issue.

3. The Continuing Violations Doctrine Tolls the Statute of Limitations.

The Nation's claims are also tolled under the continuing violations doctrine. As a general matter, the "[s]tatutes of limitations . . . are intended to keep stale claims out of the courts," and "[w]here the challenged violation is a continuing one, the staleness concern disappears." *Havens*

¹⁷⁷ *Id.* ¶ 112 (citing Letter from Vivek H. Murthy, U.S. Surgeon General to Colleague (Aug. 2016) (on file with https://perma.cc/VW95-CUYC)).

¹⁷⁸ See id. ¶ 115.

¹⁷⁹ *Id*. ¶ 106.

¹⁸⁰ *Id.* ¶ 139.

¹⁸¹ *Id.* ¶ 104.

Realty Corp. v. Coleman, 455 U.S. 363, 380 (1982). Under the doctrine, "[t]he statute of limitations for a continuing tort generally runs from the date of the last tortious act." Gross v. United States, 676 F.2d 295, 300 (8th Cir. 1982). "This doctrine is rooted in general principles of common law and is independent of any specific action" and "is premised on the equitable notion that the statute of limitations should not begin to run until a reasonable person would be aware that his or her rights have been violated." Sierra Club v. Okla. Gas & Elec. Co., 816 F.3d 666, 674 (10th Cir. 2016) (quoting Davidson v. Am. Online, Inc., 337 F. 3d 1179, 1184 (10th Cir. 2003)); see also Hensley v. City of Columbus, 557 F.3d 693, 697 (6th Cir. 2009); Guba v. Huron Cty., 600 F. App'x 374, 379 (6th Cir. 2015) (describing the doctrine as "a common[]law limited exception to the accrual of a cause of action"). Courts in Oklahoma have applied the doctrine in continuing nuisance cases and noted its applicability in cases of medical malpractice. See, e.g., Cole v. Asarco, Inc., No. 03-CV-327, 2010 U.S. Dist. LEXIS 17741, at *24–29 (N.D. Okla. Feb. 24, 2010); Burlington N. & Santa Fe Ry. Co. v. Grant, 505 F.3d 1013, 1028 (10th Cir. 2007); Wing v. Lorton, 261 P.3d 1122, 1126 n.1 (Okla. 2011).

Continuous tortious activity is exactly what the Nation has alleged. In particular, the Nation alleges a decades-long concerted and intentional effort by Defendants to increase their revenue that created and perpetuated an opioid crisis. Indeed, a one-time violation would not have created this wide-spread public health epidemic and, critically, Defendants' deceptive acts have continued unabated to this day.¹⁸²

Simply put, this is not a case involving a few isolated "discrete actions" by the Defendants. *Cf. Colby v. Herrick*, 849 F.3d 1273, 1280 (10th Cir. 2017) ("A plaintiff may not use the continuing violation theory to challenge discrete actions that occurred outside the

 $^{^{182}}$ Am. Compl. $\P\P$ 4, 14, 149, 225, 232, 257–62, 263–94, 290–91, 300, 309, 315.

limitations period even though the impact of the acts continues to be felt." (citation omitted)), overruled on other grounds by Baker v. Bd. of Regents of Kan., 991 F.2d 628, 633 (10th Cir. 1993). To the contrary, Defendants' concerted actions were that of a long-running, nationwide campaign that continues to cause harm to the Nation. The Nation alleges that—even today—Defendants continue to act tortiously by misrepresenting the safety and effectiveness of their products and failing to meet their obligations to monitor and control the closed system of opioid distribution. 183

Once again, factual issues clearly exist that preclude a ruling on the statute of limitations issue prior to discovery. These factual issues include when the Nation knew or should have known that it was suffering harm due to Marketing Defendants' misconduct, whether Marketing Defendants' misconduct is so intertwined so as to constitute a continuous wrong, and whether Marketing Defendants took actions that constitute a fraudulent concealment.

For this reason and the reasons further outlined above, the Court should reject Marketing Defendants' statute of limitations argument.

VII. THE NATION'S CLAIMS DO NOT FAIL FOR LACK OF SERVICE AND/OR PERSONAL JURISDICTION.

Amneal argues that this Court should dismiss all claims against it due to (1) improper service of process, ¹⁸⁴ and (2) lack of personal jurisdiction. ¹⁸⁵ Neither argument supports dismissal.

First, under the Federal Rules of Civil Procedure, after asserting a claim, a plaintiff has ninety days to serve a defendant (and longer for good cause). *See* Fed. R. Civ. P. 4(m). The

¹⁸³ *Id*.

¹⁸⁴ AB at 2, 3.

¹⁸⁵ AB at 3–7.

Nation first asserted a claim against Amneal in its First Amended Complaint, which it filed on July 9, 2018. Without a good cause showing, the Nation therefore has until October 9, 2018 to serve Amneal. See id.; 6(a)(1); 6(a)(6). That date has not yet passed. Thus, the Nation's claims do not fail for lack of service of process. 186

Second, Amneal's jurisdictional argument should not result in dismissal because a motion to substitute is pending. Amneal's argument boils down to an assertion that Amneal Pharmaceuticals, Inc. "is a holding company and has not manufactured, sold, promoted[,] or supplied any prescription medications, including prescription opioid medications." Assuming arguendo that Amneal's assertion is true, the Court need only substitute Amneal Pharmaceuticals, Inc. (the named holding company) with Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals of New York, LLC (which manufacture, sell, promote, and/or supply prescription opioid medications in Oklahoma). It is the Nation's understanding that all three entities are represented by the same counsel and are aware of the basis for the Nation's claims. As other MDL plaintiffs have done, the Nation attempted to resolve this issue without Court intervention by substituting the Amneal holding company with the correct entities by consent. The Nation was able to resolve similar motions filed by CVS and Walgreen's in this manner. 188 However, Amneal has withheld consent. Accordingly, the Nation has had to file a contested motion to substitute. Substitution is a more appropriate and efficient avenue for resolving this dispute than dismissal, which would merely result in the Nation filing a separate lawsuit.

¹⁸⁶ It is possible that Amneal actually is complaining that it was required to respond to the complaint before service was completed. However, that is due to a specific order of this Court, see Case Management Order No. 6, not any act or omission by the Nation.

¹⁸⁷ Declaration of Sheldon V. Hirt, attached to AB.

¹⁸⁸ Both CVS and Walgreens moved to dismiss their holding companies on jurisdictional grounds. The Nation was able to resolve both motions consensually. See Unopposed Motion to Dismiss CVS Health Corporation, No. 1:18op-45459-DAP (N.D. Ohio) ECF No. 81; Unopposed Motion to Dismiss Walgreens Boots Alliance, Inc., which dismisses Walgreens Boots Alliance, Inc. without prejudice, No. 1:18-op-45459-DAP (N.D. Ohio) ECF No. 82.

Substitution reaches the same result while also "conserve[ing] judicial resources, reduc[ing] duplicative service . . . and promot[ing] the just and efficient conduct of [the National Prescription Opiate Litigation]." *See* Case Management Order One § 1.a.

Thus, the Court should deny Amneal's motion.

VIII. DEFENDANTS' ASSERTIONS THAT THE NATION HAS FAILED TO ALLEGE ACTIONABLE MISCONDUCT ARE WITHOUT MERIT.

A. The Nation States a Claim for Public Nuisance.

An Oklahoma court, applying Oklahoma law, and courts in five other opioid cases have denied motions to dismiss plaintiffs' public nuisance claims.¹⁸⁹ The Court should do so as well here. Ignoring these cases, especially the prior Oklahoma decision, Defendants assert various arguments that misstate the Nation's allegations and the law in an attempt to dismiss the Nation's public nuisance claims.¹⁹⁰ Specifically, Defendants assert that the Nation's public nuisance claims should be dismissed because, they argue, (1) Oklahoma limits nuisance claims to those involving the use of property and not those related to the sale of a product,¹⁹¹ (2) the Nation fails to allege interference with a "public right," and (3) the Nation fails to allege that Defendants controlled the instrumentality of the nuisance.¹⁹³

Defendants' arguments are without merit. First, despite citing Oklahoma's public nuisance statute, Defendants ignore the plain language of that statute in arguing that public

¹⁸⁹ See Okla. Litig. at 1; W. Va. Litig. I at 14–19; W. Va. Litig. II at 27; Wash. Litig. at 3–4; N.Y. Litig. I, 2018 WL 3115102, at *21–22; N.Y. Litig. II at 12–14; N.H. Litig. at 27–28; Ohio Litig. at 7.

¹⁹⁰ While Manufacturers and Distributors present substantive arguments as to why the Nation's nuisance claim should be dismissed, Generic Manufacturer Defendants and Pharmacy Defendants incorporate by reference arguments they presented during briefing in cases involving Summit County, *See* GB at 23) and Broward County (PB at 13). These prior cases did not involve any analysis of Oklahoma law, and instead involved questions under Ohio and Florida law. As such, Generic Manufacturer Defendants' and Pharmacy Defendants' incorporation of these prior briefs should be rejected. Moreover, given their failure to cite to any Oklahoma law in their opening briefs, these Defendants should be precluded from doing so for the first time on reply.

¹⁹¹ MB at 34–38

¹⁹² DB at 19–21

¹⁹³ DB at 15–16.

nuisance requires a connection to property. Second, Defendants' exclusion of the collective health, safety, and security of the Nation's citizens from the definition of "public rights" strains credulity. To the contrary, the law of public nuisance in Oklahoma (and elsewhere) exists precisely to remedy harms to these areas. Third, Defendants are *the only ones* who can control and abate this public nuisance, as only they can shut off the flood of prescription opioid pills flowing to those who do not need them, either prescribed based upon Defendants' false or misleading statements and/or diverted due to Defendants' negligence.

1. Oklahoma Statutory and Case Law Recognize that Public Nuisance Claims Can Be Products-Based.

In arguing the Nation's nuisance claims should be dismissed, Defendants' principal argument is that Oklahoma limits public nuisance claims to those involving the misuse of, or interference with, land and real property, and prohibit claims such as those here, which are based on the sale of products. However, Defendants collectively fail to cite to a single Oklahoma case that holds that products-based nuisance claims are prohibited. Conversely, Oklahoma's nuisance statutes impose no such restriction, and several Oklahoma courts have expressly permitted products-based nuisance claims to proceed.

a. Oklahoma's Nuisance Statute Does Not Prohibit Products-Based Nuisance Claims.

The Oklahoma nuisance law provides, in pertinent part:

§ 1. Nuisance defined

A nuisance consists in unlawfully doing an act, or omitting to perform a duty, which act or omission either:

First. Annoys, injures or endangers the comfort, repose, health, or safety of others; or

¹⁹⁴ See, e.g., MB at 35.

Second. Offends decency; or

Third. Unlawfully interferes with, obstructs or tends to obstruct, or renders dangerous for passage, any lake or navigable river, stream, canal or basin, or any public park, square or highway; or

Fourth. In any way renders other persons insecure in life, *or* in the use of property, provided, this section shall not apply to preexisting agricultural activities.

Okla. Stat. tit. 50, § 1 (emphasis added).

A "public nuisance" is separately defined as "one which affects at the same time an entire community or neighborhood, or any considerable number of persons, although the extent of the annoyance or damage inflicted upon the individuals may be unequal." Okla. Stat. tit. 50, § 2.

Certainly, nothing in the plain language of the statute limits a public nuisance claim to those that are related to property, nor does anything exclude claims related to products.

Defendants' acts and omissions plainly "[a]nnoy[], injure[] or endanger[] the comfort, repose, health, or safety of others," and "render[] other persons insecure in life." The fact that Section 1, Fourth, refers to insecurity "in life, or in the use of property" indicates that public nuisances are not limited to those that are property-related. Similarly, by the plain language of the statutory definition of "public nuisance," the Complaint states a claim for public nuisance because it alleges that that Defendants' conduct "inflicted annoyance and damage upon" the Nation's "entire community." That is plainly alleged here.

b. Case Law from Oklahoma and Other Jurisdictions Supports the Concept of Products-Based Public Nuisance Claims.

Courts in two Oklahoma cases, as well as numerous courts outside of Oklahoma, have recognized products-based public nuisance claims. Most relevant is an Oklahoma court's recent decision (Ex. C) in similar opioid litigation brought by the Oklahoma Attorney General, in which

 $^{^{195}}$ See Am. Compl. ¶¶ 419–32, 452–64.

the court held that the State's complaint stated a claim for public nuisance. Similar to the present allegations, the State of Oklahoma's nuisance allegations were exclusively products-based. Separately, in 1998, an Oklahoma state court permitted the State's nuisance claims against tobacco manufacturers to proceed, despite the fact that the claims were, once again, products-based. *See* Order and Opinion, *State of Oklahoma v. R.J. Reynolds, et al.*, No. CJ 96-1499 (Okla. Dist. Ct. Nov. 5, 1998) (Ex. L).

Given that the Oklahoma Supreme Court has not addressed the issue, this Court must predict how that court would rule. *Conlin v. Mortg. Elec. Registration Sys., Inc.*, 714 F.3d 355, 358 (6th Cir. 2013). It is not only appropriate, but unavoidable, for this Court to be guided by the decisional law from not only the Oklahoma courts, but also other state courts. *See, e.g., Pittman v. Experian Info. Sols., Inc.*, 901 F.3d 619, 636 (6th Cir. 2018) (in predicting how the state supreme court would decide the issue, the federal court "may use the decisional law of the state's lower courts, other federal courts construing state law, . . . and other jurisdictions on the 'majority' rule." (citation omitted)).

Similar to the Oklahoma court, state courts in six other jurisdictions have permitted such claims to proceed in opioid cases. Defendants simply ignore all these cases, *including the Oklahoma case*, even though some Defendants were parties in some of these cases, and Purdue was a party in all of them.

Most recently, a New Hampshire court rejected Purdue's attempt to limit nuisance claims to those involving the use of property. *See N.H. Litig.* at 27–28 (Ex. D). Specifically, the court held that Purdue's argument was "too narrow [a] reading of the law." *Id.* at 27. In rejecting

¹⁹⁶ Ohio Litig. (Ex. E); Alaska Litig. (Ex. F); N.Y. Litigs. I, 2018 WL 3115102; N.Y. Litig. (Ex. G); Wash. Litig. (Ex. H); W. Va. Litigs. I & II (Exs. J, K). The Washington court's decision, holding that the state stated a claim for public nuisance, supersedes the district court's decision in Everett Litig., 2017 WL 4236062, dismissing the City's public nuisance claim, which proved to rest on too narrow a reading of the statutory definition.

Purdue's argument, the court held that, under New Hampshire law, a nuisance is "behavior which unreasonably interferes with the health, safety, peace, comfort or convenience of the general community." *Id.* (emphasis in original). The court concluded that the use of the phrase "behavior" suggested that a nuisance was more than the use of real property. *Id.* Oklahoma's use of the phrases "act or omission" in its definition of a nuisance mirrors New Hampshire's use of the phrase "behavior" and supports the same conclusion the New Hampshire court reached: that nuisances involve more than the use of real property.

The state court's decision in the Alaska opioid case, which held that the complaint stated a public nuisance claim, also resonates with respect to the Nation's claims in this case:

The State's third claim for relief alleges Purdue has created a public nuisance. The Alaska Supreme Court has indicated its agreement with federal common law defining a public nuisance as an unreasonable interference with a right common to the general public, such as a significant interference with the public health, the public safety, the public peace, the public comfort or the public convenience.

The State alleges Purdue's conduct, as described in the complaint, has "been a substantial factor" in creating a public health crisis and state of emergency in Alaska. The State alleges opioid use, overuse, and addiction has injured the State by causing deaths, overwhelming medical resources and emergency rooms, increasing illegal activity and law enforcement activities, increasing costs for medical care of infants born with neonatal abstinence syndrome and requiring foster treatment, and incurring significant expenses in addiction treatment.

The court finds the facts as alleged could reasonably be construed as demonstrating a significant interference with the public health, the public safety, the public peace, the public comfort or the public convenience and therefore an interference with a right common to the general public.

The State has alleged facts sufficient to state a claim for public nuisance.

Alaska Litig. at 8 (Ex. F).

The court's decision in the New York opioid case also resonates:

Here, it is alleged that the plaintiffs have been damaged not only by the illegal use of opioids but also by their legal use, consistent with the manufacturer defendants' marketing and promoting. As to such legal use, it is at least arguable that the manufacturer defendants were in a position to anticipate or prevent the claimed

injuries; it does not seem unfair, therefore, to hold them potentially accountable. The court is doubtful, in any event, whether a discussion of proximate cause in a case based on negligence should even apply in a case based on public nuisance. "[W]here the welfare and safety of an entire community is at stake, the cause need not be so proximate as in individual negligence cases." As for the manufacturer defendants' claim that the plaintiffs have failed to plead substantial interference with a public right, it suffices to note the defendants' failure to establish why public health is not a right common to the general public, nor why such continuing, deceptive conduct as alleged would not amount to interference; it can scarcely be disputed, moreover, that the conduct at the heart of this litigation, alleged to have created or contributed to a crisis of epidemic proportions, has affected "a considerable number of persons."

N.Y. Litig. I, 2018 WL 3115102, at *22; see also N.Y. Litig. II at 22 (Ex. G) (same).

Likewise, in the Washington opioid case, the court stated:

10. Purdue moves to dismiss the State's public nuisance claim for failure to plead a relationship to real property. The Court finds that the statute is quite clear that it applies to interference with life *or* property, and that interference with real property is not required. The Court further finds that, even if there were such a requirement, the State has made threshold allegations that would connect Purdue's conduct to real property in the State. The Court will therefore deny Purdue's motion to dismiss

Wash. Litig. at 3 (Ex. H).

Finally, in the West Virginia opioid case, the court stated:

- 54. "Generally, [public nuisance] has been described as 'the doing or the failure to do something that injuriously affects the safety, health, or morals of the public, or works some substantial annoyance, inconvenience, or injury to the public."
- 55. The Court concludes the Amended Complaint sufficiently alleges Defendants either did something or failed to do something that injuriously affected the safety, health, and morals of the public, or worked some substantial annoyance, inconvenience, or injury to the public which is the accepted definition of "public nuisance."
- 59. The Court concludes that the Amended Complaint's allegations fit squarely within the definition under West Virginia law. The State alleges Defendants "failed to do something," that is, they failed to provide effective controls against the diversion of controlled substances and failed to design and operate a system that discloses suspicious orders of controlled substances, failed to live up to industry standards each one a failure that "injuriously affects the safety, health, or morals of the public."

W. Va. Litig. I at 15–16 (Ex. J) (citations omitted).

The common thread between all of these decisions is the court's recognition that products-based public nuisance claims are permissible and Defendants' arguments that public nuisance claims are limited to those involving property have no merit. Defendants ignore all of these cases, as well as other cases from other jurisdictions where courts have allowed non-opioid products-based public nuisance claims to proceed.¹⁹⁷

Defendants assert that the Nation seeks to "expand" the public nuisance doctrine "in ways wholly unsupported by existing Oklahoma case law," and "plead a theory of public nuisance that is unrecognizable in the eyes of Oklahoma." However, the two Oklahoma court decisions described above belie that assertion. Defendants offer the Court a selection of Oklahoma public nuisance cases involving interference with the use and enjoyment of real property, 199 but none of these cases exclude injuries *not* connected with real property, and neither does Okla. Stat. tit. 50, § 2 (2017). *Cf. W. Va. Litig. I* at 15 n.8 (Ex. J) ("Our Supreme Court has stated that a nuisance has a 'broad definition' and that 'nuisance is a flexible area of the law that

¹⁹⁷ See Illeto v. Glock Inc., 349 F.3d 1191, 1213–15 (9th Cir. 2003) (plaintiff was allowed to proceed past the motion to dismiss stage with public nuisance claim alleging defendants created an illegal secondary market for guns); City of New York v. A-1 Jewelry & Pawn, Inc., 247 F.R.D. 296, 343 (E.D.N.Y. 2007) (permitting public nuisance claim against members of the gun retailing industry whose marketing and sales practice lead to the diversion of large numbers of firearms into the illegal secondary gun market); People v. ConAgra Grocery Prods. Co., 227 Cal. Rptr. 3d 499, 534–35 (Cal. Ct. App. 2017), cert. docketed (July 18, 2018) (permitting public nuisance claim based on the defendants' promotion of lead paint); KS&E Sports v. Runnels, 72 N.E.3d 892, 903 (Ind. 2017) (guns); City of Gary ex rel. King v. Smith & Wesson Corp., 801 N.E.2d 1222, 1231-32 (Ind. 2003) (public nuisance claim proper under Indiana law where City alleged that gun manufacturers, distributors, and dealers knowingly participated in a distribution system that unnecessarily and sometimes even intentionally provided guns to criminals, juveniles, and others who may not lawfully purchase them); James v. Arms Tech., Inc., 820 A.2d 27, 51 (N.J. Super. Ct. App. Div. 2003) (public nuisance claim based on theory that defendants fostered an illegal secondary gun market was allowed to proceed); City of Cincinnati v. Beretta U.S.A. Corp., 768 N.E.2d 1136, 1142-44 (Ohio 2002) (appellants adequately pled their public nuisance claim because "under the Restatement's broad definition, a public nuisance action can be maintained for injuries caused by a product if the facts establish that the design, manufacturing, marketing, or sale of the product unreasonably interferes with a right common to the general public"), superseded on other grounds by statute; Tuft v. Rocky Mountain Enters., Inc., No. 080902325, 2009 WL 611707 (Utah Dist. Ct. Mar. 4, 2009) (guns).

¹⁹⁸ MB at 33, 34. This brief excises references by Defendants to the Blackfeet Nation and to Montana law. ¹⁹⁹ MB at 35–36.

is adaptable to a wide variety of factual situations." (citation omitted)); *Smith & Wesson Corp.*, 801 N.E.2d at 1232 (stating that any real property focus in public nuisance cases "is due to the happenstance of how the particular . . . actions arose and not to any principle of law.").

Defendants must turn to other states to find purported case law to support their position. Courts in these cases, of course, are not applying Oklahoma law and are in any event distinguishable. For example, State of Rhode Island v. Lead Industries Ass'n, 951 A.2d 428 (R.I. 2008), was a products liability case. Moreover, there, unlike here, the defendants did not control where their products went. Camden Cty. Bd. of Chosen Freeholders v. Beretta, U.S.A. Corp., 273 F.3d 536, 540 (3d Cir. 2001) was a gun case and the court dismissed the public nuisance claim not because it rejected product-based public nuisance claims, but because, among other things, there were no allegations that the defendants violated any legal obligations. City of Perry v. Proctor & Gamble Co., 188 F. Supp. 3d 276, 291 (S.D.N.Y. 2016), and Detroit Board of Education v. Celotex Corp., 493 N.W.2d 513, 520 (Mich. Ct. App. 1992), are distinguishable because those cases involved private nuisances, not public nuisance claims. Similarly, City of St. Louis v. Benjamin Moore & Co., 226 S.W.3d 110 (Mo. 2007) was a real property case in which the court viewed the purported nuisance as a private tort. None of these cases particularly help Defendants.

c. The Nation Separately Alleges Property-Based Public Nuisance.

Finally, even if Defendants' arguments that Oklahoma limits nuisance claims to ones involving property were correct, the Nation's public nuisance claims should not be dismissed because the Nation does, in fact, allege that Defendants' actions harmed the Nation's use and

²⁰⁰ Marketing Defendants also cite to the Third Restatement of Torts to support their position. MB at 37 n.11. However, Marketing Defendants fail to note that Oklahoma has not adopted the Third Restatement as it is still in draft form.

enjoyment of real property. Specifically, the Nation alleges that Defendants' actions caused "increased crime, property damage, and public blight."²⁰¹ It is axiomatic that allegations of "property damage" and "public blight" establish the connection to real property Defendants inaccurately claim is missing. So too do the Nation's allegations that Defendants' actions have "increased crime." Defendants have forced the Nation to expend considerable resources to address the opioid epidemic, ²⁰² including those of law enforcement to keep the Nation's property safe from the increased crime directly resulting from Defendants' actions. In sum, the Nation's public nuisance claims allege interference with "the comfort, repose, health, and safety of the Nation" as well as its "use of property."²⁰³

For all of the reasons discussed above, the Court should reject Defendants' arguments that the Nation's products-based nuisance claim should be dismissed.

2. The Nation Adequately Alleges Interference with a Public Right.

Distributors further contend that the Complaint fails to state a nuisance claim because there are no allegations that Distributors interfered with a public right. Distributors' argument is without merit and ignores the allegations of the Complaint, which describes at least six separate public rights with which Distributors have interfered:

- To be free from reasonable apprehension of danger to person and property;²⁰⁴
- To be free from the spread of disease within the community, including the disease of addiction and other diseases associated with widespread illegal opioid use;²⁰⁵
- To be free from the negative health and safety effects of widespread illegal drug sales on premises in and around the Nation;²⁰⁶

²⁰¹ Am. Compl. ¶ 22.

²⁰² *Id*. ¶ 426.

²⁰³ *Id.* ¶¶ 427, 460.

 $^{^{204}}$ Id. ¶ 453.

²⁰⁵ *Id*.

²⁰⁶ *Id*.

- To be free from blights on the community created by areas of illegal drug use and opioid sales;²⁰⁷
- To live and work in a community in which local businesses do not profit from using their premises to sell products that serve the criminal element and foster a secondary market of illegal transactions;²⁰⁸ and
- To live and work in a community in which community members are not under the influence of narcotics unless they have a legitimate medical need to use them.²⁰⁹

The Nation need only demonstrate interference with a single public right in order to state a claim for public nuisance.

In the opioid context, a New York court recently held that public health was a right common to the general public and was sufficient to satisfy this element of a nuisance claim. *N.Y. Litig. I,* 2018 WL 3115102, at *22; *N.Y. Litig. II* at 12–14 (Ex. G). Similarly, a West Virginia court held that the State of West Virginia adequately pled interference with a public right in alleging that Cardinal interfered with a common right "to be free from unwarranted injuries, addictions, diseases and sicknesses" *W. Va. Litig. I* at 17 (Ex. J). These formulations of public rights are consistent with the Nation's allegation that Defendants have interfered with a public right "to be free from the spread of disease within the community, including the disease of addiction and other diseases associated with widespread illegal opioid use." ²¹⁰

Other courts have recognized similar public rights as a basis for stating a public nuisance claim. *See Bubalo v. Navegar, Inc.*, No. 96 C 3664, 1998 WL 142359, at *1 (N.D. III. Mar. 20, 1998) (holding that a desire to be "free from disturbance and reasonable apprehension of danger" is a sufficient public right with which to plead a public nuisance claim); *Pestey v. Cushman*, 788 A.2d 496, 505 (Conn. 2002) (explaining that "[p]ublic nuisance law is concerned with the

²⁰⁷ Id.

²⁰⁸ *Id*.

²⁰⁹ *Id*.

 $^{^{210}}$ *Id*. ¶ 453.

interference with a public right, and cases in this realm typically involve conduct that allegedly interferes with the public health and safety").

As described above, under Oklahoma law, a nuisance includes any act or omission that "annoys, injures or endangers the comfort, repose, health, or safety of others" or "in any way renders other persons insecure in life." Okla. Stat. tit. 50 § 1 (2017). Similarly, the Restatement identifies three circumstances that may "sustain a holding that an interference with a public right is unreasonable":

- a. [w]hether the conduct involves a significant interference with the public health, the public safety, the public peace, the public comfort or the public convenience; or
- b. whether the conduct is proscribed by a statute, ordinance or administrative regulation; or
- c. whether the conduct is of a continuing nature or has produced a permanent or long-lasting effect, and, as the actor knows or has reason to know, has a significant effect upon the public right.

Restatement (Second) of Torts § 821B. The Nation alleges that Defendants' conduct harms public health and safety, was in violation of RICO and the Lanham Act, and has produced long-lasting and significant effects within the Nation.²¹¹ The Court should deny Defendants' motion to dismiss for failure to allege interference with a public right.

3. The Nation Adequately Alleges That Defendants Exerted Sufficient Control Over Opioids to Establish Liability.

Distributors and Pharmacies argue that the Nation's public nuisance claims fail because they did not control the opioids at the time of the nuisance.²¹² This, however, is a factual dispute. Their argument, moreover, essentially repackages their causation argument. In other words, Distributors and Pharmacies argue that they cannot be held responsible because intervening

²¹¹ See, e.g., Am. Compl. ¶¶ 353–418, 422, 425, 454, 457.

²¹² DB at 15–16; PB at 13. As noted above, Pharmacy Defendants merely incorporate by reference arguments they made in unrelated briefing, which involves no citation to Oklahoma law.

actors allegedly caused the nuisance. Specifically, they contend the nuisance did not occur until individual opioid users ingested the opioids which the Defendants no longer controlled.²¹³ Their argument on control fails for at least the same reasons that their arguments on causation and intervening cause fail.

Moreover, Distributors' and Pharmacies' "control" argument misses the mark. The Nation is not alleging that the nuisance occurred when individual users ingested opioids; the Nation alleges that the nuisance occurred when Distributors and Pharmacies:

- "facilitate[ed] the diversion of prescription opioids by selling, distributing, or dispensing, or facilitating the sale, distribution, or dispensing of, prescription opioids from premises on or around the Nation to unauthorized users . . .";²¹⁴
- "fail[ed] to implement effective controls to guard against theft, diversion, and misuse of prescription opioids from legal supply chains";²¹⁵
- "fail[ed] to design and operate an adequate system to detect, halt, and report suspicious orders of prescription opioids";²¹⁶ and
- "us[ed] property for repeated unlawful sales of prescription opioids." ²¹⁷

The Nation further alleges that at all times, Distributors and Pharmacies "had the power to shut off the supply of illicit opioids into the Nation" and "possessed the right and ability to control the nuisance-causing outflow of opioids from pharmacy locations or other points of sale into the surrounding Nation."²¹⁸ The Nation's allegations that Distributors and Pharmacies controlled the opioids at all relevant times must be accepted as true at this motion to dismiss stage.

²¹³ *Id*.

²¹⁴ Am. Compl. ¶ 452(a).

²¹⁵ *Id*. ¶ 452(b).

²¹⁶ *Id.* ¶ 452(c).

²¹⁷ *Id*. ¶ 452(d).

 $^{^{218}}$ *Id.* ¶ 462.

Distributors' and Pharmacies' role in creating a nuisance in and around the Nation with respect to opioids mirrors other defendants' conduct in gun cases where nuisance claims were often permitted to proceed. For instance, in *James v. Arms Technology*, the court addressed this very argument. 820 A.2d at 52. There, the court rejected gun manufacturers', distributors', and retailers' arguments that a public nuisance claim could not stand because defendants did not control the firearms when they were illegally used. *Id.* Instead, the court noted that the nuisance was the intentional or negligent creation and fueling of an illegal gun market that unreasonably interfered with the public welfare. *Id.* The "instrumentality" controlled by the defendants was the creation and supply of the illegal market. *Id.* Similarly, in *Tuft*, the nuisance was not created by a non-party's illegal use of the gun. 2009 WL 611707. Instead, the gun distributor's negligent and unlawful sale of the weapon created the nuisance. *Id.*

Distributors cite a single Tenth Circuit case in support of their argument. Burlington stands for the unremarkable proposition that "control" is an element of a nuisance claim. The Nation does not dispute this general premise. However, as was the case with the gun defendants, here, the Nation alleges that it was Distributors' and Pharmacies' actions and omissions that occurred (or did not occur) when they were in control of the opioid drug, prior to the sale of drugs to individual users that resulted in an illegal market for opioids, which in turn created a nuisance in and around the Nation. Indeed, the gravamen of the Nation's complaint is that the Distributors, and Pharmacies, and Diversion Manufacturors failed to properly control the opioids in their possession and thus caused, fueled, and continues to fuel the opioid crisis.

At the very least, whether the nuisance was created at the time Defendants failed to take actions to curb this illegal market, at the time individuals ingested opioids, or at both or some

²¹⁹ DB at 15 (citing Burlington N. & Santa Fe Ry. Co. v. Grant, 505 F.3d 1013, 1026 (10th Cir. 2007)).

other time, and whether Defendants had any requisite level of control rendering them liable for the nuisance alleged by the Nation, involve questions of fact inappropriate for a motion to dismiss.

Accordingly, Defendants' motion to dismiss based on an alleged lack of control should be rejected.

B. The Nation States a Negligence Claim Against All Defendants.

The Nation has asserted negligence and negligence per se claims against all Defendants.

Courts in five other opioid cases have denied motions to dismiss based on negligence. This

Court should do so here as well.

Count V of the Complaint contains the Nation's negligence and negligence per se claims against Marketing Defendants.²²¹ Those claims center on Marketing Defendants' misstatements and misleading statements about the risks of long-term use of prescription opioids for chronic pain. Count VIII of the Complaint contains the Nation's negligence and negligence per se claims against Diversion Defendants.²²² Those claims center on Diversion Defendants' failure to prevent diversion of prescription opioids from the legitimate chain of supply.

Defendants primarily argue that the negligence claims should be dismissed because:

(1) the Complaint fails to establish a duty on the part of the Defendants;²²³ and (2) the Complaint fails to state a negligence per se claim.²²⁴ Additionally, Distributor Defendants argue that the negligence claims asserted against them should be dismissed because: (1) the Complaint fails to allege that Distributor Defendants breached any duty owed to the Nation;²²⁵ and (2) Oklahoma's

²²⁰ See Alaska Litig. at 9–10 (Ex. F); N.Y. Litig. I, 2018 WL 3115102, at *25–27; N.Y. Litig. II at 17–21 (Ex. G); Wash. Litig. at 3 (Ex. H); Everett Litig., 2017 WL 4236062, at *8–9; W. Va. Litigs. I & II (Exs. J, K).

²²¹ Am. Compl. ¶¶ 433–445.

²²² Am. Compl. ¶¶ 451–464.

²²³ See, e.g., MB at 17; DB at 10; PB at 8.

²²⁴ MB at 31; DB at 11.

²²⁵ DB at 15.

"Innocent Seller" statute prohibits any negligence claims against Distributor Defendants.²²⁶ Defendants' arguments either are wrong on the law or are not appropriate to adjudicate on a motion to dismiss.²²⁷

1. Legal Standards

Under Oklahoma law, negligence consists of "(1) a duty owed by the defendant to protect plaintiff from injury, (2) failure to fulfill that duty and (3) injuries to plaintiff proximately caused by defendant's failure to meet the duty." *Fargo v. Hays-Kuehn*, 352 P.3d 1223, 1227 (Okla. 2015). Negligence per se exists where (1) the plaintiff's injury was caused by the defendant's violation of a statute, (2) the alleged injury was of the type intended to be prevented by the statute, and (3) the injured party was part of the class intended to be protected by the statute. *Howard v. Zimmer, Inc.*, 299 P.3d 463, 467 (Okla. 2013).

As demonstrated below and throughout this Consolidated Opposition, the Nation has adequately stated claims for both negligence and negligence per se, and Defendants' attempts to dismiss these claims must be rejected.

2. Defendants Owe Duties to the Nation.

The Complaint alleges that each Marketing Defendant "has a duty under Federal and Oklahoma law to exercise reasonable care in marketing and selling opioids." Marketing Defendants' common law duty is a "duty to make a full and fair disclosure as to the matters about which they choose to speak." Marketing Defendants are also under a statutory duty not

²²⁶ *Id.* at 9–10.

²²⁷ In arguing that the Nation has failed to state a claim for negligence, Defendants repeat their erroneous arguments that the Nation has failed to allege causation or injury. These arguments lack merit for the same reasons discussed in the relevant sections of this brief. *See* §§ III, IV, *supra*.

²²⁸ Am. Compl. ¶ 99; see id. ¶ 435.

²²⁹ *Id*. ¶ 101.

to engage in misleading labeling, which includes advertising.²³⁰ Inasmuch as these are statutory duties, violations constitute negligence per se.

The Complaint alleges that each Diversion Defendant "has a common law duty to exercise reasonable care under the circumstances" and "assumes a duty, when it speaks publicly about opioids, to speak accurately."²³¹ The Complaint *separately* alleges that Oklahoma and federal laws and regulations impose "legal obligations" on Diversion Defendants "to prevent diversion"²³² and "create a standard of conduct to which [they] must adhere."²³³ These statutes and regulations include Oklahoma's Uniform Controlled Dangerous Substances Act ("Oklahoma CSA"), Okla. Stat. tit. 63 § 2, and the duties imposed in the statute and its implementing regulations, and the FCSA, 21 U.S.C. §§ 801–971.²³⁴

Disciplinary sanctions may be imposed on pharmacists for knowing violations of these and other Oklahoma and federal laws. It is critical that the Nation hold them to account for violating their common law and statutory obligations, and prevent them from violating those obligations going forward, because, as the Complaint alleges, "[p]harmacists are the 'last line of defense' in keeping drugs from entering the illicit market[,]" and "are meant to be the drug experts in the healthcare delivery system, and as such have considerable duties and responsibility in the oversight of patient care."

Defendants do not directly dispute the Complaint's allegation of breach of a duty.

Instead, Defendants disavow a duty that the Complaint does not allege—"a duty to anticipate or

²³⁰ 21 U.S.C. §§ 331(a), 352 (2016).

²³¹ Am. Compl. ¶ 162.

²³² *Id.* ¶¶ 14, 98.

 $^{^{233}}$ Id. ¶ 163.

²³⁴ *Id*. ¶¶ 166–199.

 $^{^{235}}$ *Id.* ¶ 187.

prevent the criminal, intentional, or reckless conduct of others."²³⁶ Thus, Defendants devote much of their briefs to arguing that neither the Oklahoma CSA nor the FCSA can be used to establish their liability for negligence. As set forth below, the Nation disagrees with this contention, as these statutes can be used as the basis for a negligence per se claim (and even short of that, the statutes most certainly can be used as *evidence* of the standard of care that Defendants were expected to meet, had they exercised reasonable care²³⁷). However, ultimately, it is a red herring as Defendants clearly owe the Nation duties under the common law.

Under Oklahoma law, a "duty of care is an obligation owed by one person to act so as not to cause harm to another." *See Lowrey v. Echostar Satellite Corp.*, 160 P.3d 959, 964 (Okla. 2007); *see also* Okla. Stat. Ann. tit. 76 § 1 (2018). Oklahoma courts recognize that "a person owes a duty of care to another person whenever the circumstances place the one person in a position towards the other person such that an ordinary prudent person would recognize that if he or she did not act with ordinary care and skill in regard to the circumstances, he or she may cause danger of injury to the other person." *Lowrey*, 160 P.3d at 964. The "most important" consideration in determining the existence of a duty of care is "foreseeability of harm" to the plaintiff and a defendant owes a duty of care to any plaintiff who is foreseeably endangered by defendant's conduct with respect to all risks that make the conduct unreasonably dangerous. *Id.* Put another way, the Oklahoma Supreme Court has noted that "a legal duty arises when a human endeavor creates a generalized and foreseeable risk of harming others." *Delbrel v. Doenges*

²³⁶ See, e.g., MB at 17; DB at 14–15; PB at 9. Of course, Defendants should have (at the very least) foreseen, and could have prevented, this conduct, which their actions and omissions enabled and indeed facilitated.

²³⁷ Tort plaintiffs frequently rely on duties imposed by statutes or regulations to establish the applicable standard of care in common law negligence cases, or that violation of a regulation is evidence of a breach of duty. *See*, *e.g.*, *Hull v. Chevron U.S.A.*, *Inc.*, 812 F.2d 584, 589–90 (10th Cir. 1987) (affirming district court's jury instruction that the violation of a federal regulation may be evidence of negligence, and reading regulations to jury); *Corporan v. Wal-Mart Stores E.*, *LP*, No. 16-2305-JWL, 2016 WL 3881341, at *5 (D. Kan. July 18, 2016) ("to the extent that plaintiff references the federal [Gun Control Act] to define the standard of care—and references a violation of that statute as evidence of breach—[Kansas law] permits that approach.").

Bros. Ford, Inc., 913 P.2d 1318, 1321 (Okla. 1996) (citing approvingly the Supreme Court of Florida's decision McCain v. Fla. Power Corp., 593 So. 2d 500, 503 (Fla. 1992)).

Here, the foreseeability of the widespread harms to the Nation that were caused by Defendants' actions cannot be questioned, especially at the motion to dismiss stage. The potential that opioids could cause such harms was so foreseeable that federal and state laws were enacted in an attempt to curb those harms from occurring. Indeed, the DEA has worked to provide guidance to Defendants about the steps they should be taking to prevent the harms that have befallen the Nation. Yet, more concerned with their profits than with avoiding harm to the Nation, Defendants ignored the existence of suspicious orders they were aware of and failed to report this information to the DEA or Oklahoma agencies. 239

Furthermore, as summarized by an Oklahoma court, Section 302(B) of the Restatement (Second) of Torts, provides that:

An act of omission may be negligent if the actor realizes or should realize that it involves an unreasonable risk of harm to another through the conduct of the other or a third person which is intended to cause harm, even though such conduct is criminal.

Brewer v. Murray, 292 P.3d 41, 47–48 (Okla. Ct. App. 2012) (quoting Joyce v. M & M Gas Co., 672 P.2s 1172, 1173–74 (Okla. 1983)) (reversing grant of summary judgment and concluding that issues of fact existed as to whether defendant owed duties to plaintiff).

In this case, the Nation's allegations establish a common law duty for all Defendants based on their actions. With respect to Marketing Defendants, the Complaint includes, among other things, allegations that Marketing Defendants made affirmative misstatements about (a) the risks of addiction to prescription opioids, ²⁴⁰ (b) the risks associated with increasing opioid

²³⁸ *See* Am. Compl. ¶ 201–02.

²³⁹ See, e.g., id. ¶ 336.

²⁴⁰ See, e.g., Am. Compl. ¶ 104.

dosages,²⁴¹ (c) the levels of opioid abuse,²⁴² and (d) the steps they are taking to curb the opioid epidemic.²⁴³ By committing these acts, Marketing Defendants assumed a general duty to others to exercise the care of a reasonable person to protect them against an unreasonable risk of harm to them arising out of the affirmative act. *Compare* Complaint, *with*, *Boyle v. ASAP Energy*, *Inc.*, 408 P.3d 183, 193 (Okla. 2017) (adopting a "reasonable care" standard and noting that a duty exists where the defendants "knew or should have known" their actions would create an unreasonable risk of harm to others). Moreover, Marketing Defendants' duty of care extends to the foreseeable range of dangers created by their product. *City of Spokane v. Monsanto Co.*, No. 2:15-CV-00201-SMJ, 2016 WL 6275164, at *9 (E.D. Wash. Oct. 26, 2016).

Diversion Defendants had a common law duty to prevent the diversion of dangerous opioid products. By supplying and continuing to supply quantities of prescription opioids in and around the Nation with actual or constructive knowledge that the opioids were being diverted from the legitimate supply chain and consumed by the Nation's citizens for non-medical purposes, Diversion Defendants violated common law duties owed to the Nation.

Several other courts in opioid-related litigations have found the complaints in such actions sufficient to state a claim for negligence. For instance, in *City of Everett*, a federal court found that the City adequately stated a duty owed by the defendants under § 302(B) of the Restatement (Second) of Torts. *Everett Litig.*, 2017 WL 4236062, at *4. The court held that allegations that the defendants had supplied opioids to suspicious pharmacies enabled the illegal diversion of opioids and aided criminal activity were sufficient to establish the defendants' duty. *Id.* ("The Court finds that Everett has adequately pled that Purdue engaged in an affirmative act

²⁴¹ See, e.g., id. ¶ 120.

²⁴² See, e.g., id. ¶ 122.

²⁴³ See, e.g., id. ¶ 143.

which created or exposed Everett to a high degree of risk of harm. If Everett is able to prove these allegations, they trigger a legal duty under Section 302B and Washington law."). The Nation's Complaint sets forth similar allegations.²⁴⁴

Similarly, a West Virginia court accepted as sufficient to state a valid claim of negligence allegations that the defendants had engaged in affirmative conduct under circumstances where they "knew or should have known that the distribution of addictive controlled substances in such amounts in such areas would be diverted and/or improperly used thereby creating an unreasonable risk of harm and damage to others " W. Va. Litig. I at 12 (Ex. J); see also W. Va. Litig II at 17 (Ex. K). The affirmative conduct was the "heavy distribution and sale of addictive controlled substances to Pill Mill pharmacies in unusually large amounts for the population base " Id. The court held that a violation of the West Virginia CSA could form the basis of a negligence claim by constituting either negligence per se or evidence of negligence. W. Va. Litig. I at 12–14 (Ex. J); W. Va. Litig II at 19–22 (Ex. K). Here, the Complaint includes similar allegations. 246

Most recently, a New York court rejected opioid manufacturers' and distributors' argument that they owed no duty to New York counties. *N.Y. Litig. I*, 2018 WL 3115102, at *26–27; *see also N.Y. Litig. II* at 18–20 (Ex. G). The court held that the manufacturers and distributors had a common law duty not to deceive. *N.Y. Litig. I*, 2018 WL 3115102, at *26; *see also N.Y. Litig. II* at 19–21 (Ex. G). The court also held that the plaintiffs alleged facts sufficient to support the existence of a duty of care. *N.Y. Litig. I*, 2018 WL 3115102, at *26; *see also N.Y. Litig. II* at 19 (Ex. G). Specifically, the plaintiffs sufficiently pled the existence of this duty by

²⁴⁴ See Am. Compl. ¶ 14, 166, 168, 173, 175–76, 225, 228, 259–61, 277–78, 287, 468, 470, 472.

²⁴⁵ As described below, Defendants' conduct constitutes not only negligence but negligence per se and the Nation should be able to proceed on both theories. *See* § VIII.VB, *infra*.

²⁴⁶ See Am. Compl. ¶ 14, 166, 168, 173, 175–76, 225, 228, 259–61, 277–78, 287, 468, 470, 472.

alleging that the defendants had "knowledge of the actual risks and benefits of their products, including their addictive nature, which they did not disclose . . . [despite being] in the best position to protect the plaintiffs" against the amounts expended to combat the opioid crisis. *N.Y. Litig. I*, 2018 WL 3115102, at *26; *see also N.Y. Litig. II* at 19 (Ex. G).

As set forth above, Oklahoma imposes the same common law duties on Defendants as New York and West Virginia do. Accordingly, as the New York and West Virginia courts did, this Court should reject Defendants' arguments that they owe no duties to the Nation.²⁴⁷

3. The Complaint Alleges Defendants Breached Their Duties.

The Complaint alleges that Marketing Defendants made misstatements or misleading statements about the risks of prescribing opioids to treat chronic pain, and failed to state the magnitude of those risks accurately,²⁴⁸ and that they knew or should have known that their statements were misleading.²⁴⁹ The Complaint's allegations include examples of misstatements or misleading statements by Marketing Defendants.²⁵⁰

It is particularly remarkable that Diversion Defendants contend that the Nation does not allege a breach of duty when the Complaint specifically states that Diversion Defendants "understood their duties and violated them anyway."²⁵¹ The Complaint alleges that Distributors, while acknowledging their duties to police the legitimate chain of supply so as to prevent

²⁴⁷ Defendants' cherry-picking of select cases involving firearms does not support their argument that they have no duty. *See*, *e.g.*, MB at 19. In the cases cited by Defendants, in which courts found no duty on the part of gun manufacturers, the courts' decisions were based on the their conclusions that the negligence claims were focused on the actions of criminals, which the gun manufacturers had no duty to control. *See*, *e.g.*, *District of Columbia v. Beretta*, *U.S.A.*, *Corp.*, 872 A.2d 633, 639–45 (D.C. 2005). As discussed throughout, the Nation's claims are not premised on the actions of any third parties but are instead based on the specific pattern of conduct engaged in by each Defendant. Indeed, in the context of firearms litigation, courts permitted claims based on gun manufacturers' and distributors' own actions to proceed past the pleading stage. *See*, *e.g.*, *City of Cincinnati v. Beretta*, *U.S.A. Corp.*, 768 N.E. 2d at 1144.

²⁴⁸ Am. Compl. ¶¶ 102–24.

²⁴⁹ *Id.* ¶¶ 138–39; see also id. ¶¶ 4–5.

²⁵⁰ *Id*. ¶¶ 149–51.

²⁵¹ *Id.* ¶¶ 200, 239.

unlawful diversion of prescription opioids,²⁵² failed and continue to fail to do so, and that Pharmacies, despite knowing "of the risks and harms of filling prescriptions for non-medical purposes,"²⁵³ and "understanding of the risks and harms of prescription opioid diversion,"²⁵⁴ failed and continue to fail to fulfill their "duty to prevent . . . diversion."²⁵⁵

Thus, Defendants' contentions that the Nation does not allege that they breached duties they owed to the Nation is patently incorrect.

4. Defendants' Conduct Constitutes Negligence Per Se.

The Complaint also states claims for negligence per se against all Defendants. As stated above, under Oklahoma law, negligence per se exists where: (1) the claimed injury was caused by the violation of a statute; (2) the injury was of the type intended to be prevented by the statute; and (3) the injured party was one of the class intended to be protected by the statute. *Howard*, 299 P.3d at 467. In *Howard*, the Oklahoma Supreme Court held that a negligence per se claim could be based on a violation of the Federal Food, Drug, and Cosmetic Act ("FDCA") despite the lack of a private cause of action in the FDCA. *Id.* at 472–73. Significantly, the question of whether a particular statutory violation may support a claim for negligence per se is an issue of state law, even when the statute involved is a federal statute, because the negligence per se claim is a state-law claim.

Here, Defendants' violations of the Oklahoma CSA and FCSA constitute negligence per se. First, as discussed above, the violations of the Oklahoma CSA and FCSA caused harm to the Nation. *See* § IV, *supra*. If Marketing Defendants had not engaged in a pattern of marketing marred by misrepresentations, and had Diversion Defendants adhered to their statutory

 $^{^{252}}$ *Id.* ¶¶ 200–62.

 $^{^{253}}$ Id. ¶ 237.

 $^{^{254}}$ *Id.* ¶ 257.

²⁵⁵ *Id*. ¶ 263.

obligations to prevent the diversion of prescription opioids, the Nation would not have suffered the harms alleged in the Complaint.

Second, these statutes impose standards that were designed to avoid the harm suffered by the Nation. Among other things, the Oklahoma CSA imposes on Defendants requirements to prevent the illegal diversion of opioids. Okla. Stat. tit. 63 § 2. Such requirements are clearly meant to prevent the very crisis Defendants have caused and are fueling.

Finally, the Nation and its citizens are among the class of persons the statutes were enacted to protect. Other courts examining similar statutes have stated that the purpose of controlled substances acts is to "control a societal evil." *Johnson v. State of Delaware*, 587 A.2d 444, 452 (Del. 1991) (quoting *Traylor v. State of Delaware*, 458 A.2d 1170, 1178 (Del. 1983)). Elaborating, the court stated its awareness "that the organized traffic in illegal drugs is a serious problem, causing not only debilitating effects in those who use such substances, but fostering additional crimes." *Id.*; *see also United States. v. Picklesimer*, 585 F.2d 1199, 1201 (3d Cir. 1978) (noting that purpose of CSA is to "control the illegal manufacture and distribution of substances which . . . have a 'substantial and detrimental effect on the health and general welfare of the American people"); *Schlobohm v. Rice*, 510 N.E.2d 43, 46 (Ill. Ct. App. 1987) (noting that purpose of controlled substances act is to "curb drug abuse"). Thus, the statutes were clearly enacted for the benefit of the public at large, of which the Nation is indisputably a part.

In arguing that the Nation cannot use the FCSA and Oklahoma CSA as the predicate for a negligence per se claim, Defendants selectively refer to portions of the Complaint, while simply ignoring a multitude of other relevant provisions. For instance, Marketing Defendants argue that two sections of the FCSA dealing with reporting requirements to the federal government cannot form the basis of a negligence per se claim because they do not "include the [Nation] in a

protected statutory class or provide[] protection to the [Nation] for [its] asserted injuries."²⁵⁶
However, the case Marketing Defendants cite to support their assertion actually demonstrates why a negligence per se claim is proper, as it shows that the CSA was designed to provide protections to the public at large.²⁵⁷ In any event, the two sections of the CSA on which Marketing Defendants focus are two of many provisions referenced throughout the Complaint that Defendants have violated. These statutory provisions and regulations include ones requiring Defendants to employ a system to inform the DEA of suspicious orders,²⁵⁸ and to provide effective controls and procedures to guard against the theft and diversion of opioids.²⁵⁹ Similar requirements are imposed by Oklahoma law.²⁶⁰

Marketing Defendants also argue that the Supreme Court and Sixth Circuit have held that "state law claims premised on the [Marketing Defendants'] alleged violation of the CSA—and the FDCA—are preempted by federal law[.]"²⁶¹ However, the Supreme Court decision they cite, *Buckman Co. v. Plaintiffs' Legal Committee*, deals only with a "fraud on the FDA" claim and nothing in the opinion suggests that all state law claims based on the CSA or FDCA are preempted. *See* 531 U.S. 341 (2001). In fact, as noted above, the Oklahoma Supreme Court, in answering a certified question from the Tenth Circuit, expressly held that negligence per se claims could be based on a violation of the FDCA. *Howard*, 299 P.3d at 467.

²⁵⁶ See MB at 31–32 (discussing 21 U.S.C. § 823 (2017) and 21 U.S.C. § 827 (2009)).

²⁵⁷ MB at 32 (citing *Carmack v. UPMC*, No. G-D-14-013571, 2015 Pa. Dist. & Cnty. Dec. LEXIS 14730, at *26–27) (Pa. D. & C. Jan 12, 2015).

²⁵⁸ See Am. Compl. ¶ 168 (citing 21 C.F.R. § 1301.74(b).

²⁵⁹ See id. ¶ 171.

 $^{^{260}}$ See id. ¶¶ 179–85.

²⁶¹ MB at 32.

5. Oklahoma's "Innocent Seller" Statute Does Not Apply.

Finally, Distributors argue that the Nation's negligence claims against them are barred by Oklahoma's "Innocent Seller" statute. That statute, which was enacted in 2014, limits a non-manufacturing product seller's liability in negligence actions that are related to defects in the product. This type of statute is designed to protect sellers of allegedly defective products who were not responsible for the defect as they did not design, assemble, or inspect the product at issue. *See Williams v. Biomet, Inc.*, No. 3:13-CV-1955-RLM-CAN, 2016 WL 806559, at *2 (N.D. Ind. Feb. 29, 2016) (analyzing Indiana's version of statute).

This statute has no application to the present facts because Distributors' negligence is not premised on the sale of opioids per se, but its failure to take steps to prevent the diversion of opioids.²⁶⁴ While Oklahoma courts have not addressed this issue, courts in other jurisdictions that have analyzed similar "Innocent Seller" statutes have held that these types of statutes do not protect entities such as the Distributors from claims that "depend on their own culpable conduct, rather than simply on their status as sellers of an allegedly defective product." *Williams*, 2016 WL 806559, at *2. Because the Nation's claims are not products liability claims, nor are they in any way related to allegations that the opioids distributed by Distributors were defective, Oklahoma's "Innocent Seller" statute has no application to the present facts and Distributor Defendants' argument should be rejected.

C. The Nation States a Claim for Unjust Enrichment.

Defendants argue that the Nation's claims for unjust enrichment should be dismissed because: (1) Defendants have received no benefit from the Nation, including because the

²⁶² DB at 9–10.

²⁶³ Okla. Stat. tit. 76, § 57.2(G).

²⁶⁴ See, e.g., Am. Compl. ¶ 468.

Nation's payment of healthcare services and the externalities of Defendants' conduct are not a benefit to Defendants;²⁶⁵ (2) the Nation's unjust enrichment claims are derivative of, and should fail for the same reasons as, the Nation's other claims;²⁶⁶ and (3) if any of the Nation's other claims are viable, the Nation cannot recover based on unjust enrichment.²⁶⁷ Defendants are wrong.²⁶⁸

1. An Oklahoma Court Has Held That Oklahoma Stated an Unjust Enrichment Claim Under Oklahoma Law In an Opioids Case Similar to This Case.

"[T]he governing substantive law in diversity actions is state law," *Atria v. Vanderbilt Univ.*, 142 F. App'x 246, 250 (6th Cir. 2005) (citation omitted), which in this case is Oklahoma. That proposition would seem too obvious to bear mention, except that Marketing Defendants and Distributors rely extensively on cases from other jurisdictions in assailing the Nation's unjust enrichment claims.²⁶⁹ In doing so, they overlook the fact that an Oklahoma court has already

²⁶⁵ MB at 40–41; DB at 23–24; PB at 14. As defined in the Complaint, externalities are "the costs of the harm caused by" Defendants' acts and omissions.

²⁶⁶ DB at 23.

²⁶⁷ PB at 14 n.12.

²⁶⁸ Defendants also contend that (1) the Nation has failed to allege facts to support quasi-contract, *see* MB at 33–34, (2) the Nation cannot recover municipal expenditures under an unjust enrichment theory, *see id.* at 41–42, and

⁽³⁾ the Nation's unjust enrichment claims fail absent a showing of causation, see id. at 16.

On the first point, the Nation is not asserting a claim in quasi-contract, which is related to, but separate from, unjust enrichment. *In re Amending & Revising Okla. Unif. Jury Instructions—Civil*, 217 P.3d 620, (Okla. 2009) (promulgating model instructions for quasi-contract claims, but not for unjust enrichment claims due to their equitable nature). This argument is therefore a non-sequitur.

The Nation responds to the other two points in text. See §§ II.C (municipal cost recovery rule), III (causation), supra.

²⁶⁹ MB at 16, 42 (citing *Perry v. Am. Tobacco Co., Inc.*, 324 F.3d 845 (6th Cir. 2003) (Tennessee law)); *id.* at 17, 42 (citing *In re Darvocet, Darvon*, & *Propoxyphene Prods. Liab. Litig.*), 756 F.3d 917, 937 (6th Cir. 2014) (Florida); *City of Miami v. Bank of Am. Corp.*, 800 F.3d 1262, 1288 (11th Cir. 2015) (Florida), *rev'd on other grounds*, 137 S. Ct. 1296 (2017)); *id.* at 16 (citing *In re Light Cigarettes Mktg. Sales Practices Litig.*, 271 F.R.D. 402, 418 (D. Me. 2010) (Maine and District of Columbia)); *id.* at 41–42 (citing *Ashley Cty. v. Pfizer, Inc.*, 552 F.3d 659 (8th Cir. 2009) (Arkansas)); *id.* at 41 (citing *Oregon Laborers-Employers Health & Welfare Tr. Fund v. Philip Morris Inc.*, 185 F.3d 957, 963 (9th Cir. 1999) (Oregon); *Serv. Emps. Int'l Union Health & Welfare Fund v. Philip Morris, Inc.*, 249 F.3d 1068 (D.C. Cir. 2001), *aff'g in part, rev'g in part*, 83 F. Supp. 2d 70 (D.D.C. 1999) (District of Columbia); *Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris, Inc.*, 171 F.3d 912, 934 n.23 (3d Cir. 1999) (collecting cases applying non-Oklahoma unjust enrichment law)); DB at 24 (citing *Allegheny Gen. Hosp. v. Philip Morris, Inc.*, 228 F.3d 429 (3d Cir. 2000) (Pennsylvania)). Distributors also cite a brief of an unnamed party in an unnamed case in an unnamed court. *See id.* ("Chicago Br., Dkt. 571-1 at Part V").

decided the precise issue presented here in an opioids case—holding that the State of Oklahoma stated an unjust enrichment claim against four of the Marketing Defendants (Purdue, Teva, Allergan, and Watson) and other defendants. *Okla. Litig.* (Ex. C). Six of the seven courts that have considered the question under the laws of other states have also held that the government plaintiff stated unjust enrichment claims.²⁷⁰

In the absence of an Oklahoma Supreme Court decision addressing the question, this Court must predict how that court would rule, and in making that prediction—the "Erie guess," see Conlin v. Mortg. Elec. Registration Sys., Inc., 714 F.3d 355, 358 (6th Cir. 2013)—it is not only appropriate, but unavoidable, that the Court be guided by the decisional law from the Oklahoma court and the other state courts described above. See, e.g., Pittman v. Experian Info. Sols., Inc., No. 17-1677, 2018 WL 4016604, at *10 (6th Cir. Aug. 23, 2018); Managed Health Care Assocs., Inc. v. Kethan, 209 F.3d 923, 929 (6th Cir. 2000). That law supports the Nation's claims for unjust enrichment, and fatally undercuts the Defendants' motion to dismiss those claims for failure to state a claim.

2. The Complaint Sufficiently Alleges a Benefit to Defendants.

Under Oklahoma law, "unjust enrichment is a condition which results from the failure of a party to make restitution in circumstances where it is inequitable; i.e., the party has money in its hands that, in equity and good conscience, it should not be allowed to retain." *Harvell v. Goodyear Tire & Rubber Co.*, 164 P.3d 1028, 1035 (Okla. 2006) (footnote omitted). In order to prove unjust enrichment, a plaintiff must establish four elements: "(1) the unjust (2) retention of

²⁷⁰ Alaska Litig. (Ex. F), N.Y. Litig. I, 2018 WL 3115102; N.Y. Litig. II (Ex. G), Everett Litig. 2017 WL 4236062, W. Va. Litigs. I & II (Ex. J, K). In Chicago Litig., 211 F. Supp. 3d at 1084, the district court dismissed the City's unjust enrichment claim upon determining that the City had not supplied information sufficient to identify pharmacies swept up in the City's allegations against the manufacturers. The City supplied the required information, after which the case was transferred to this MDL as Case No. 1:17-op-45169. The City then filed a further amended complaint asserting the unjust enrichment claim. No motion to dismiss the claim is pending.

(3) a benefit received (4) at the expense of another." *S. Rock Inc. v. Summers*, No. 6:11-CV-257-RAW, 2012 WL 6722356 (E.D. Okla. Nov. 15, 2012); *see also N.C. Corff P'ship, Ltd. v. OXY USA, Inc.*, 929 P.2d 288, 295 (Okla. Civ. App. 1996) (the basis of unjust enrichment is "that in a given situation it is contrary to equity and good conscience for one to retain a benefit which has come to him at the expense of another" (quoting 66 Am. Jur. 2d *Restitution and Implied Contracts* § 3 (1973)).

Here, the Nation contends that it is unjust for Defendants' to retain funds that should be expended to pay the Nation back for amounts it was forced to expend because of the opioid crisis that Defendants caused and fuel through marketing misrepresentations and diversion for which they are responsible. The Nation seeks "restitution of all expenditures by the Nation resulting from all Defendants' conduct,"271 including costs to the healthcare, criminal justice, social services, welfare, and education systems. The Nation alleges that Defendants have retained benefits at the Nation's expense, and that it would be inequitable to allow Defendants to retain these benefits. For example, the Complaint alleges that "[t]he Nation has expended substantial amounts of money in an effort to remedy or mitigate the societal harms caused by [Defendants] ... [which] have helped sustain [Defendants'] businesses ... by paying for what may be called [Defendants'] externalities ... [while Defendants] made substantial profits ... [and] continue to receive considerable profits. These allegations state a claim for unjust enrichment under Oklahoma law because they establish "(1) the unjust (2) retention of (3) a benefit received (4) at the expense of another," see S. Rock Inc. v. Summers, No. 6:11-CV-257-RAW, 2012 WL

²⁷¹ Am. Compl. ¶ 24.

²⁷² *Id.* ¶ 431. *See id.* at 138 § f (Prayer for Relief) (restitution and disgorgement—Marketing Defendants); *id.* at 138 § i (restitution and disgorgement—Diversion Defendants). The Nation likewise alleges, that Diversion Defendants' "conduct was the cause-in-fact and proximate cause of injuries and damages to the Nation, including but not limited . . . increased costs for the healthcare, criminal justice, social services, welfare, and education systems, as well as the cost of lost productivity and lower tax revenues." *Id.* ¶ 476.

²⁷³ *Id.* ¶ 448–50 (Marketing Defendants), 481–84 (Diversion Defendants).

6722356 (E.D. Okla. Nov. 15, 2012), and that Defendants have received "a benefit which has come to him at the expense of another," *i.e.*, the Nation, *see N.C. Corff P'ship, Ltd. v. OXY USA, Inc.*, 929 P.2d 288, 295 (Okla. Civ. App. 1996) (quoting 66 Am. Jur. 2d *Restitution and Implied Contracts* § 3 (1973)).

Defendants dispute that the Nation alleges that Defendants received a "benefit" from the Nation. In support of this position, they argue that they did not benefit from the Nation's payment of healthcare services because they would not typically be required to pay for the Nation's Members' healthcare, and phrased differently, the externalities of Defendants' conduct are too attenuated to establish a benefit for unjust enrichment purposes.²⁷⁴ Defendants are, again, wrong.

As multiple courts have held, the Nation's allegations that healthcare costs and other "externalities" to which Defendants refer were caused by Defendants' conduct, and that it would be unjust to require the Nation rather than the Defendants to bear those costs, state a quintessential claim for unjust enrichment. For example, in the *Everett* opioid case, the defendants, seeking dismissal of the City's unjust enrichment claim, argued that it had not received a benefit from the City as required to state a claim. 2017 WL 4236062, at *8. In response, the City argued that the payment of "the 'so-called externalities' of a defendant's conduct" can establish the benefit required. *Id.* at *9. The court agreed with the City and denied the motion to dismiss the claim. *See id.*

In White v. Smith & Wesson, 97 F. Supp. 2d 816, 829 (N.D. Ohio 2000), a firearms case, the court stated:

Plaintiffs allege that they have conferred a benefit upon Defendants, *i.e.*, that the City has paid for what may be called the Defendants' externalities—the costs of the harm caused by Defendants' failure to incorporate safety devices into their

²⁷⁴ MB at 40–41; DB at 23–24; PB at 14.

handguns and negligent marketing practices. Plaintiffs further allege that Defendants are aware of this obvious benefit, and that retention of this benefit is unjust. Plaintiffs have stated a claim and thus, at this stage of the litigation, their claim survives.

Id. at 829. In City of Los Angeles v. JP Morgan Chase & Co., No. 2:14-cv-04168-ODW (RZx), 2014 WL 6453808 (C.D. Cal. Nov. 14, 2014), the City sought restitution from a bank of the costs of harms—"externalities"—that the City alleged the bank caused it to absorb by its alleged discriminatory lending. The City alleged that, in absorbing these costs, it conferred benefits on the bank. Id. at *10. The court concluded, "in line with similar decisions from trial courts across the country," that the City had "properly alleged a benefit to state a theory of recovery for restitution." Id.; see also City of Boston v. Smith & Wesson Corp., No. 199902590, 2000 WL 1473568, at *18 (Mass. Super. Ct. July 13, 2000) (sustaining an unjust enrichment claim at the pleading stage based on "externalities" that the City covered due to gun manufacturer's actions); City of New York v. Lead Indus. Ass'n, Inc., 597 N.Y.S.2d 698, 700 (1993) (city stated a claim for restitution from lead paint manufacturers for its expenditures to abate the hazard that their product caused, and to treat the victims).

3. The Nation's Unjust Enrichment Claims Are Not Derivative or Duplicative of Its Other Claims.

Defendants also argue that the Nation's unjust enrichment claims must be dismissed as duplicative and derivative of its other claims. ²⁷⁵ Defendants are wrong for two reasons. First, the Nation's claims for unjust enrichment are the only claims through which it seeks disgorgement. ²⁷⁶ Thus, they are not duplicative of the Nation's other claims. *See N.Y. Litig. I*, 2018 WL 3115102, at *25; *N.Y. Litig. II* at 17 (Ex. G). Second, the Nation is permitted to plead in the alternative. *See Avery Dennison Corp. v. Four Pillars Enter. Co.*, 45 F. App'x 479, 488

²⁷⁵ DB at 23.

²⁷⁶ Am. Compl. at 138–39 ¶ f.ii, i.ii (Prayer for Relief).

(6th Cir. 2002) (per curium); see also N.C. Corff P'ship, 929 P.2d at 295 ("Oklahoma procedure clearly permits pleading alternative remedies, just as it allows alternative theories of recovery, as long as plaintiffs are not given double recovery for the same injury."); Fed. R. Civ. P. 8(e)(2) (allowing for pleading in the alternative). For these same reasons, a New York court recently denied opioid defendants' attempts to dismiss claims for unjust enrichment:

It does not appear, for purposes of this determination, that this cause of action is either derivative or duplicative of any other cause of action. As pleaded, it is the only cause of action by which the plaintiff seek disgorgement of profits . . . moreover, as New York law specifically allows for the pleading of alternative causes of action and alternative forms of relief . . . , the plaintiffs need not elect any theory over another at this preliminary stage.

N.Y. Litig. I, 2018 WL 3115102, at *25 (citation omitted); N.Y. Litig. II, at 17 (Ex. G). This Court should do the same.

4. The Availability of Remedies at Law If the Nation Succeeds on Its Other Claims Does Not Support Dismissal.

Pharmacies rely on several cases for the proposition that since unjust enrichment requires the absence of a remedy at law in Oklahoma, any viable claim for damages would foreclose unjust enrichment.²⁷⁷ However, plaintiffs are entitled to plead unjust enrichment in the alternative to legal claims. *See Avery*, 45 F. App'x at 488; *N.C. Corff P'ship*, 929 P.2d at 295; Fed. R. Civ. P. 8(e)(2). Moreover, whether a particular claim will ultimately prove "viable" has no bearing on whether the party has stated a claim, meaning that it cannot justify dismissal at the pleading stage. *See N.Y. Litig I*, 2018 WL 3115102, at *25 (holding that, "as New York law specifically allows for the pleading of alternative causes of action and alternative forms of relief. . . . , the plaintiffs need not elect any theory over another at this preliminary stage"); *N.Y. Litig II* at 17 (Ex. G) (same); *cf. Valley View Agri, LLC v. Producers Coop. Oil Mill*, No. CIV-15-1297-

²⁷⁷ PB at 14 n.12.

D, 2017 WL 1208670, at *3 (W.D. Okla. Mar. 31, 2017) (where it has yet to be determined whether plaintiff has an adequate remedy at law for damages, summary judgment in favor of defendant on plaintiff's unjust enrichment claim is premature). Thus, the Nation's unjust enrichment claims cannot be dismissed because they assert a legal remedy for Defendants' conduct in addition to unjust enrichment.

D. The Nation States a Claim for Civil Conspiracy.

Under Oklahoma law,

A civil conspiracy consists of a combination of two or more persons to do an unlawful act, or to do a lawful act by unlawful means. . . . In order to be liable the conspirators must pursue an independently unlawful purpose or use an independently unlawful means. There can be no civil conspiracy where the act complained of and the means employed are lawful.

Gaylord Entm't Co. v. Thompson, 958 P.2d 128, 148 (Okla. 1998) (footnotes omitted).

Defendants assert that the Nation does not state a claim for civil conspiracy because, they argue: (1) Defendants' actions were lawful;²⁷⁸ (2) the Nation fails to plead an agreement between the parties to the conspiracy;²⁷⁹ (3) the Nation does not plead civil conspiracy with the requisite particularity;²⁸⁰ (4) civil conspiracy cannot be based on negligence;²⁸¹ and (5) if the Nation's tort claims are dismissed, its civil conspiracy claim must fall.²⁸² As addressed in turn, Defendants are wrong on all points.

1. The Nation's Civil Conspiracy Claim Is Not Defeated by Distributors' Denial of the Nation's Allegations.

Distributors argue that the Nation cannot state a claim of civil conspiracy because they have done nothing wrong:

²⁷⁸ See DB at 26.

²⁷⁹ See PB at 13–14; DB at 25–26.

²⁸⁰ See DB at 25.

²⁸¹ See MB at 67–68; DB at 25.

²⁸² See MB at 67; PB at 13; DB at 26.

[I]t is not an "unlawful purpose" for Distributors to distribute their goods to pharmacies (the CSA explicitly allows them to do so), nor do Distributors use "unlawful means" by selling their goods to pharmacies in the manner that the CSA permits—sales about which the Distributors give full information to DEA through the ARCOS system.²⁸³

Distributors' argument fails for three reasons.

First, in making this argument, Defendants improperly go beyond the allegations of the Complaint to assert that Distributors complied with their diversion-related obligations. Facts outside the Complaint cannot be a basis for dismissal at the pleading stage. *See, e.g., Kostrzewa v. City of Troy*, 247 F.3d 633, 643 (6th Cir. 2001) ("The district court, in reviewing a motion to dismiss, may not consider matters beyond the complaint.").

Second, by definition, if the allegations underlying the Nation's claim of civil conspiracy are true—as this Court must assume in evaluating a motion to dismiss, *Iqbal*, 556 U.S. at 678—Distributors' actions were *not* lawful. *See State ex rel Elsey v. Silverthorn*, 161 P.2d 858, 860 (Okla. 1945) ("The county commissioners argue that . . . there can be no conspiracy when the acts complained of, and the means employed in doing them, are lawful. But if, as the plaintiff charges . . . they took part in a conspiracy . . . the means employed were not lawful."). Thus, the Court cannot dismiss the Nation's claim based on Distributors' assertions.

Third, the Nation *does* allege that Distributors acted in violation of law—it asserts that Distributors distributed and sold excessive quantities of dangerous opioid prescription drugs in a manner that permitted diversion into illegitimate channels of distribution and use, all in violation of their legal obligations and with predictable, devastating results to the Nation and its citizens.²⁸⁴ It is irrelevant whether Distributors complied with other laws while violating those that are the subject of the Nation's claims.

²⁸³ See DB at 26.

²⁸⁴ See generally Am. Compl.

2. The Nation Sufficiently Pleads Civil Conspiracy.

Defendants argue that the Nation fails to plead civil conspiracy fully because it fails to allege an agreement or "meeting of the minds" between Defendants.²⁸⁵ Defendants are wrong: the Nation expressly alleged an agreement between and among the Defendants, and it alleged other facts from which the existence of a conspiracy may be inferred, which is sufficient under Oklahoma law not only to allege, but to prove, a conspiracy.

Under Oklahoma law,

It is not necessary . . . to prove by direct evidence that the parties actually came together and entered into a formal agreement to do the things complained of . . . such an understanding may be shown by proof of facts and circumstances from which the existence of a conspiracy may be inferred.

State ex rel Elsey v. Silverthorn, 161 P.2d 858, 859 (Okla. 1945) (citing Democrat Printing Co. v. Johnson, 175 P. 737, 738 (Okla. 1918)). Moreover, under federal law, at the motion to dismiss stage, the Nation need only have included in its Complaint facts that, "accepted as true . . . allow[] the court to draw the reasonable [and probable] inference that the defendant is liable for the misconduct alleged," *Iqbal*, 556 U.S. at 678; *Twombly*, 550 U.S. at 557, and that provide

Democrat Printing, 175 P. at 738 (citing 5 Ruling Case Law, § 37, p 1088).

²⁸⁵ See PB at 13–14; DB at 25–26.

²⁸⁶ In fact, under Oklahoma law, all aspects of a conspiracy can be established by inference:

Conspiracies need not be established by direct evidence of the acts charged, but may and generally must be proved by a number of indefinite acts, conditions, and circumstances which vary according to the purposes to be accomplished. The very existence of a conspiracy is generally a matter of inference, deduced from certain acts of the persons accused, done in pursuance of an apparently criminal or unlawful purpose in common between them. The existence of the agreement or joint assent of the minds need not be proved directly. It may be inferred by the jury from other facts proved. It is not necessary to prove that the defendants came together and actually agreed in terms to have the unlawful purpose, and to pursue it by common means. If it be proved that the defendants pursued by their acts the same object, often by the same means, one performing one part and another [] part of the same, so as to complete it, with a view to the attainment of that same object, the jury will be justified in the conclusion that they were engaged in a conspiracy to effect that object. If, therefore, one concurs in a conspiracy, no proof of agreement to concur is necessary in order to make him guilty.

Defendants "fair notice of what the claim is and the grounds upon which it rests," *Marie v. Am. Red Cross*, 771 F.3d 344, 364 (6th Cir. 2014) (citation omitted).

Contrary to Defendants' contention, the Complaint expressly alleges the existence of a conspiracy, including concerted action and an agreement or meeting of the minds among Defendants:

- None of the Defendants would have succeeded in profiting so much from the opioid epidemic without the concerted conduct of the other parties.²⁸⁷
- Defendants agreed with each other to accomplish the unlawful purposes of marketing, selling, distributing, and retailing prescription opioids through violations of law and misrepresentations. Defendants performed numerous overt acts in furtherance of this conspiracy, including marketing, selling, distributing, and retailing prescription opioids by means of misrepresentations and omissions, violating Federal and state laws, and turning a blind eye to diversion of prescription opioids.²⁸⁸

Other allegations of the Complaint support an inference that there was a conspiracy and provide Defendants notice of the basis for the Nation's claims. Among other things, the Complaint asserts that:

- Marketing Manufacturer[s]...have engaged, and continue to engage, in a massive marketing campaign to misstate and conceal the risks of treating chronic pain with opioids. Although manufacturers are prohibited from marketing opioids through misstatements or omissions of material facts, Marketing Manufacturer[s]...did so through this campaign, which includes websites, promotional materials, conferences, guidelines for doctors, and other vehicles.²⁸⁹
- This aggressive marketing campaign enabled Marketing Manufacturer[s]... to overcome the longstanding medical consensus that opioids were unsafe for the treatment of chronic pain... and resulted in a significant increase in the number of opioids prescribed nationwide. ²⁹⁰
- In response to and in conjunction with this increased demand, Diversion Manufacturer[s] . . . continuously supplied name-brand prescription opioids and, where applicable, their generic equivalents to Distributor[s] . . ., which Distributor[s] .

²⁸⁷ See Am. Compl. ¶ 490.

²⁸⁸ See id. ¶ 491.

 $^{^{289}}$ *Id*. ¶ 4.

²⁹⁰ *Id.* ¶¶ 5, 486.

- . . then continuously supplied to Pharmac[ies] . . ., which then dispensed these prescription opioids to consumers, including the Nation's citizens. ²⁹¹
- Diversion...Defendants...have legal obligations to combat diversion. Diversion
 Defendants have routinely and continuously violated these obligations, and instead
 have taken advantage of the massively increased demand for prescription opioids for
 non-medical uses by profiting heavily from the sale of opioids that they knew or
 should have known were being diverted from the legitimate supply chain to
 illegitimate channels of distribution.²⁹²
- Without Marketing Manufacturer[s']... misrepresentations, which created demand, Diversion Defendants would not have been able to sell the increasing number of orders of prescription opioids for non-medical purposes throughout the Nation. ²⁹³
- Without Diversion Manufacturer[s']... and Distributor[s']... supply of prescription opioids, Pharmac[ies]... would not have been able to fill the increasing number of orders of prescription opioids for non-medical purposes throughout the Nation.²⁹⁴

Because the allegations in the Complaint either directly assert or support an inference that there was a conspiracy, including an agreement, among Defendants, the Nation has adequately pled civil conspiracy, Defendants have received adequate notice of those claims, and Defendants motion to dismiss for failure to plead conspiracy adequately must be denied.

3. The Nation Pleads Civil Conspiracy with the Requisite Level of Particularity.

Defendants also argue that the Nation is required to plead civil conspiracy with particularity, and it has not done so.²⁹⁵ However, that pleading requirement is only applicable to civil conspiracy claims in which fraud is the underlying tort. *See Raven Res., LLC v. Legacy Bank*, No. CJ-08-282, 2008 WL 8153487 (Okla. Dist. Aug. 1, 2008), *aff'd*, 229 P.3d 1273. Here, the Nation's civil conspiracy allegations are based on all of its claims against Defendants other than negligence—not just fraud. Thus, the Nation is required only to give Defendants "fair

²⁹¹ *Id*. ¶ 487.

 $^{^{292}}$ *Id*. ¶ 14.

²⁹³ *Id*. ¶ 488.

²⁹⁴ See id. ¶ 489.

²⁹⁵ See DB at 25.

notice of what the claim is and the grounds upon which it rests." *See Marie*, 771 F.3d at 364. The Nation has done so. *See* § V, *supra*. Moreover, to the extent that the Nation relies on fraud as the basis for civil conspiracy, it has pled fraud with the requisite particularity. *See id*.

4. It Is Immaterial That the Nation's Civil Conspiracy Claim Cannot be Based on Negligence.

Defendants next argue that the Nation's civil conspiracy claim cannot be based on negligence. However, Defendants' argument does not and cannot carry the day for Defendants. In addition to negligence, the Nation alleges four discrete legal claims against Defendants—violations of RICO (Counts I and II); violations of the Lanham Act (Count III); nuisance (Counts IV and VII); and unjust enrichment (Counts VI and IX). Thus, it is immaterial for purposes of the Nation's civil conspiracy claim that the Nation also alleges that Defendants were negligent.

5. The Nation's Civil Conspiracy Claims Should Not Be Dismissed Based on the Purported Insufficiency of the Nation's Other Claims.

Defendants also argue that the Nation's civil conspiracy claims automatically fail because the Nation is unable to prove its other claims, and civil conspiracy can only survive in the presence of an independent tort.²⁹⁸ Defendants are wrong for two reasons.

First, although civil conspiracy does require an independent tort, a complaint need only provide Defendants "fair notice of what the claim is and the grounds upon which it rests"; it need not prove it. *See Marie*, 771 F.3d at 364. As established herein, the Nation has sufficiently provided Defendants notice of its claims. *See* § V, *supra*.

²⁹⁶ See MB at 67–68; DB at 25.

 $^{^{297}}$ See Am. Compl. ¶¶ 353–432, 446–64, 479–84.

²⁹⁸ See MB at 67; PB at 13; DB at 26.

Second, a plaintiff ultimately need only prove an independent tort against one member of the conspiracy. *See Barsh v. Mullins*, 338 P.2d 845, 847 (Okla. 1959). Here, the Nation alleges civil conspiracy against all Defendants,²⁹⁹ and twelve of those named in the Complaint did not move to dismiss.³⁰⁰ Thus, the Court can only dismiss the Nation's conspiracy claims on this basis if the Court (1) dismisses every one of the Nation's other claims against every one of Defendants that moved to dismiss, which the Nation demonstrates herein is not warranted, and (2) *sua sponte* dismisses every one of the Nation's other claims against the twelve non-moving parties. Otherwise, the Court must reject Defendants' motion to dismiss the conspiracy claims.

E. The Nation Has Properly Alleged RICO Violations.

Defendants' motions largely consist of recycled arguments and a misapplication of the case law. In essence, Distributors, Pharmacies, and Generic Manufacturers argue that the Nation has: (1) failed to allege a direct injury; (2) cannot recover for damages that flow from personal injury; (3) cannot recover for damages incurred as a sovereign; (4) failed to allege predicate acts; and (5) failed to allege participation in an enterprise. Marketing Defendants focus on the Nation's supposed failure to allege an injury to "business or property." 301

The federal RICO Act was enacted to "protect[] the public from those who would unlawfully use an 'enterprise' (whether legitimate or illegitimate)" to commit unlawful activity. *Cedric Kushner Promotions, Ltd. v. King*, 533 U.S. 158, 164 (2001) (citation omitted); *see also*

²⁹⁹ Am. Compl. ¶¶ 485–93 (Count X).

³⁰⁰ Those Defendants are: SAJ Distributors; Anda Pharmaceuticals, Inc.; Anda, Inc.; Smith Drug Co.; The Harvard Drug Group, LLC; H. D. Smith, LLC; The Drug Warehouse; May's Drug Store; Med-X Corp.; Getman-Apothecary Shoppe, Inc.; Langsam Health Services, LLC; and Olympia Pharmacy.

³⁰¹ The Defendants' RICO arguments are located in their briefs at DB at 3–5; PB at 7 & n.7; GB at 22; and MB at 25–27. Several of the Defendants also purport to "incorporate" arguments made in various other briefs, including briefs filed by defendants in the *Summit County* and *Blackfeet* cases. The Pharmacy Buying Association also joins and incorporates Distributors' motion. *See* ECF No. 51. Defendants' purported "incorporation" and cross-referencing about a hundred pages of briefing from different cases is not only convoluted, but also inconsistent with the Court's order regarding page limits. Nevertheless, to the extent the Court considers the briefing from these other cases, the Nation "incorporates" all of the relevant responsive briefing by the plaintiffs in those cases.

Sedima, S.P.R.L. v. Imrex Co., 473 U.S. 479, 498–99 (1985) ("RICO was an aggressive initiative to . . . develop new methods" that can be "used against respected businesses allegedly engaged in a pattern of specifically identified criminal conduct"). In fact, RICO stresses not only "the importance of undermining organized crime's influence upon legitimate businesses, but also . . . the need to protect the public from those who would run 'organization[s] in a manner detrimental to the public interest." Cedric Kushner, 533 U.S. at 165 (citation omitted) (emphasis added). In conjunction with these purposes, RICO provides for broad civil remedial purposes. Sedima, 473 U.S. at 495.

Notably, the principal sponsor of the RICO bill specifically recognized, as one of "two examples of types of problems RICO was designed to address . . . the illicit prescription drug industry." United States v. Turkette, 452 U.S. 576 at 590 (1981) (citing 116 Cong. Rec. 592 (1970)). As recognized by the Supreme Court, what was needed were "new approaches that will deal not only with individuals, but also with the economic base through which those individuals constitute such a serious threat to the economic well-being of the nation. In short, an attack must be made on their source of economic power itself, and the attack must take place on all available fronts." *Id.* at 591–92 (citation omitted). Unsurprisingly then, courts have held corporations liable under RICO—including companies involved in making or distributing highly regulated prescription drugs or addictive products—when they participate in wide-ranging enterprises that impose detrimental societal consequences. See, e.g., In re Neurontin Mktg. & Sales Pracs. Litig., 712 F.3d 21, 33–50 (1st Cir. 2013) (pharmaceutical manufacturers liable for marketing dangerous prescription drug for off-label use); United States v. Philip Morris USA, Inc., 449 F. Supp. 2d 1, 28 (D.D.C. 2006) (bench trial ruling that tobacco companies conspired with each other and used other means to deny relevant facts and profit from selling addictive product that

led to deaths, human suffering, loss, and a burden on the healthcare system). Defendants' actions here not only fit, but far exceed the level of activity found illegal under RICO.

The Nation has alleged more than sufficient facts to state plausible substantive RICO claims, pursuant to 18 U.S.C. § 1962(c), as part of the Opioid Marketing Enterprise against Marketing Defendants and the Opioid Supply Chain Enterprise against all Defendants.³⁰² "Section 1962(c) makes it unlawful 'for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity or collection of unlawful debt." *Turkette*, 452 U.S. at 580.

Thus, to state a claim under Section 1962(c), a plaintiff must plead "(1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity." *In re ClassicStar Mare Lease Litig.*, 727 F.3d 473, 483 (6th Cir. 2013) (citation omitted). Additionally, a civil RICO plaintiff "must show that the RICO violation was the proximate cause of [an] injury to their business or property." *Id.* at 484 (citation omitted). The Nation has adequately alleged each of these elements.³⁰³

³⁰² Am. Compl. ¶¶ 353–408.

³⁰³ The Nation does not have to satisfy Rule 9(b) for each of these elements. *See State Farm Mut. Auto. Ins. Co. v. Pointe Physical Therapy, LLC*, 107 F. Supp. 3d 772, 784–91 (E.D. Mich. 2015) (analyzing RICO elements as needing to be plausibly alleged, while applying the heightened pleading standard of Rule 9(b) to the mail and wire fraud predicate act claims); *Dowling v. Select Portfolio Servicing, Inc.*, No. 2:05-CV-049, 2006 WL 571895, at *9 (S.D. Ohio Mar. 7, 2006); *see also D. Penguin Bros. Ltd. v. City Nat. Bank*, 587 F. App'x 663, 666 (2d Cir. 2014) ("In the RICO context, a plaintiff must plead predicate acts sounding in fraud or mistake according to the particularity requirement of Rule 9(b); for other elements of a RICO claim—such as non-fraud predicate acts or, as relevant here, the existence of an 'enterprise'—a plaintiff's complaint need satisfy only the 'short and plain statement' standard of Rule 8(a)." (citation omitted)).

1. The Complaint Adequately Alleges Direct Injury.

Defendants argue that the Nation fails to allege a direct injury, failing to establish that

Defendants' fraudulent "predicate acts" proximately caused the Nation's injury. However,

Defendants ignore recent Sixth Circuit precedent, attempt to analogize to inapposite

U.S. Supreme Court precedent, misrepresent several of the Nation's RICO allegations in the

Complaint, and ask the Court to apply an inflexible causation test that most courts have declined to apply at the pleading stage of the litigation.

Proximate cause serves as a "judicial tool[] used to limit a person's responsibility for the consequences of that person's own acts." *Bridge v. Phx. Bond & Indem. Co.*, 553 U.S. 639, 654 (2008). All forms of proximate cause analysis demand "some direct relation between the injury asserted and the injurious conduct alleged." *Holmes v. Sec. Investor Prot. Corp.*, 503 U.S. 258, 268 (1992). *Holmes* provides a framework for analyzing the policy sought to be protected by the proximate cause doctrine, ensuring that: (1) damages can be properly and efficiently apportioned; (2) no party recovers excessively; and (3) the directly injured are able to vindicate the law by bringing suit to enforce it. *Holmes*, 503 U.S. at 269–70. Here, the Nation's damages were directly caused by Defendants' actions. Especially at this early phase of the litigation, the analysis from *Holmes v. Sec. Inv'r Prot. Corp.*, 503 U.S. 258, 268 (1992) weighs in favor of finding sufficient proximate cause. This is because the Nation's damages may be properly and efficiently apportioned among Defendants, the Nation's RICO damages cannot be sought or recovered by any other party, and the Nation's recovery is necessary to vindicate the purposes underlying RICO and to deter future violations. *See Bank of Am. Corp. v. City of Miami*, 137 S.

³⁰⁴ DB at 3 (cross-referencing AmerisourceBergen Drug Corp., Cardinal Health, Inc., and McKesson Corp.'s Memo. In Support of Motion to Dismiss, *Blackfeet Tribe of the Blackfeet Indian Reservation v. AmerisourceBergen Drug Corp.*, No. 1:18-op-45749 (N.D. Ohio Aug. 31, 2018), ECF No. 23. ("BF") at 3–4); MB at 15; GB at 23.

Ct. 1296, 1306 (2017) (relying on *Holmes* to remand a case involving a lengthy causal chain rather than defining the precise bounds of proximate causation at the motion to dismiss stage).

The "direct injury" requirement in RICO establishes that there must be a "link between the scheme and the type of injury . . . suffered [by the plaintiff]" Wallace v. Midwest Fin. & Mortg. Servs., Inc., 714 F.3d 414, 420 (6th Cir. 2013). "What matters . . . is not whether there is a direct relationship between the plaintiff and the defendant, but whether there is a 'sufficiently direct relationship between the defendant's wrongful conduct and the plaintiff's injury" In re Volkswagen "Clean Diesel" Mktg., Sales Pracs., & Prods. Liab. Litig., MDL No. 2672 CRB (JSC), 2017 WL 4890594, at *9 (N.D. Cal. Oct. 30, 2017) (quoting Bridge, 553 U.S. at 657).

The Sixth Circuit recently addressed the RICO direct injury requirement, reversing summary judgment against a plaintiff alleging that a mortgage broker and mortgage lender substantially inflated the value of his house in an appraisal "as part of a larger scheme to secure high-interest loans." *Wallace*, 714 F.3d at 420. Having created an "illusion" of substantial home equity in the mind of the plaintiff, the plaintiff decided he could afford a renovation, after which the mortgage broker convinced him "to enter into a large option [adjustable rate mortgage ('ARM')], the unfavorable terms of which were never made clear to [the plaintiff]." *Id*. Eventually, "[t]he accruing interest outpaced [the plaintiff]'s ability to pay" and the plaintiff found himself owing more on the mortgage than the house was worth. *Id*. He therefore claimed to be "injured in the amount of the fees, interest costs, and other expenses tied to the option ARM." *Id*.

The Sixth Circuit, in reversing the district court's grant of summary judgment against the plaintiff, found the district court had an "unnecessarily rigid understanding of the case," finding it was "clear enough that the inflated appraisal itself played a significant role in the negotiations"

between the plaintiff and his mortgage broker, and extending from that point it was "certainly possible that the illusion of equity made the difference . . ." in plaintiff obtaining the ARM. *Id.* at 420. Even at summary judgment "[w]hile the illusion alone did not compel [the plaintiff] to borrow as he did here, it certainly increased the likelihood he would. Put another way, the inflated appraisal appears to be 'a substantial factor in the sequence of responsible causation' according to [the plaintiff]'s version of the facts." *Id.* at 421 (quoting *Cox v. Adm'r U.S. Steel & Carnegie*, 17 F.3d 1386, 1399 (11th Cir. 1994)); *see also Trollinger v. Tyson Foods, Inc.*, 370 F.3d 602, 618–19 (6th Cir. 2004) (refusing to dismiss "plaintiffs' multi-link chain of causation" at motion to dismiss stage).

The Nation has met its burden for these causation standards. The Complaint directly links Defendants' scheme to the injury suffered by the Nation. The Nation alleges in detail that Defendants created two association-in-fact RICO enterprises, the Opioid Marketing Enterprise and the Opioid Supply Chain Enterprise, whose acts directly injured the Nation. Marketing Defendants employed certain Front Groups and KOLs to conceal the true risks and dangers of opioids from the medical community and the public, including the Nation, and made misleading statements and misrepresentations about opioids that downplayed the risk of addiction and exaggerated the benefits of opioid use. This conduct was specifically intended to, and did, promote widespread use of dangerous, addictive opioids, causing an epidemic of addiction that injured the Nation through substantial losses of money and property that logically, directly, and foreseeably arose from the opioid-addiction epidemic. The Nation through substantial losses of money and property that logically, directly, and

³⁰⁵ Am. Compl. ¶¶ 296–352.

³⁰⁶ *Id.* ¶¶ 296–328

³⁰⁷ *Id.* ¶¶ 350–51, 378, 406.

Similarly, the Opioid Supply Chain Enterprise concealed, suppressed, and/or ignored warnings from third parties, whistleblowers, and governmental entities about the reality of the suspicious orders that the Opioid Supply Chain Defendants were filling on a daily basis—leading to diversion of hundreds of millions of doses of prescription opioids into the illicit market.³⁰⁸ This consequence—the creation of a widespread opioid epidemic—was foreseeable and expecteded, and it in turn directly and foreseeably caused the Nation to suffer substantial losses of money and property as a result of Defendants' fraudulent scheme. ³⁰⁹ See Traveler's Prop. Cas. Co. of Am. v. Actavis, Inc., 225 Cal. Rptr. 3d 5, 9 (Cal. Ct. App. 2017), review granted, 410 P.3d 1221 (Cal. 2018).

Intervening causes do not prevent a finding of proximate cause where an original tortfeasor's intentional acts specifically contemplated, planned for, and subsequently caused the intervening acts; in such circumstances, the original tortfeasor remains liable for the consequences of its action even if intervening actors negligently or intentionally cause injury. See, e.g., Neurontin Mktg., 712 F.3d at 39 ("Pfizer now argues that because doctors exercise independent medical judgment in making decisions about prescriptions, the actions of these doctors are independent intervening causes. But Pfizer's scheme relied on the expectation that physicians would base their prescribing decisions in part on Pfizer's fraudulent marketing."); Restatement (Second) of Torts § 447. For the reasons discussed above, Defendants' alleged intervening causes were themselves not only foreseeable, but also the known and intentional consequences of Defendants' actions. See § III, supra. Therefore, they do not prevent a finding of proximate cause here.

³⁰⁸ *Id*. ¶¶ 329–49. ³⁰⁹ *Id*. ¶¶ 350–51, 378, 406.

Defendants attempt to analogize the comprehensive RICO schemes detailed in the Complaint to a pair of readily distinguishable cases. In Hemi Group, LLC v. City of New York, 559 U.S. 1 (2010), a cigarette company failed to file sales reports with the State of New York. Some customers legally obligated to pay a cigarette tax to the City of New York did not do so. Without the sales reports from Hemi, the state could not pass on the information to the City, and the City then could not determine which customers had failed to pay the cigarette tax. Id. at 9. The City was thus prevented from pursuing those customers for payment without Hemi's required filing, and so the City sued Hemi claiming an injury of the amount of uncollected cigarette taxes. Id. The Supreme Court rejected the City's theory of liability "requir[ing] that we extend RICO liability to situations where the defendants fraud on a third party (the State) has made it easier for a fourth party (the taxpayer) to cause harm to the plaintiff (the city)," id. at 11, where "the only fraudulent conduct alleged here is a violation of the Jenkins Act," id. at 14, as alleging a sufficiently direct causation connection.

Defendants make much of a quote from this case, selectively extracted and then shorn of its context, that "[t]he general tendency of the law, in regard to damages at least, is to not go beyond the first step." *Id.* at 10 (alteration in original) (quoting *Holmes*, 503 U.S. at 271–72). In truth, the U.S. Supreme Court there found that "[b]ecause the City's theory of causation requires us to move *well beyond the first step*, that theory cannot meet RICO's direct relationship requirement." *Id.* The facts of *Hemi* do not provide an an appropriate parallel for this case.

By contrast to *Hemi*, the Nation alleges two longstanding and extensive RICO schemes whose express purpose was to enrich all Defendants by generating massively increased demand for and ensuring a similarly massive supply of dangerous, addictive opioids. The conduct of the

³¹⁰ DB at 3 (cross-referencing BF at 3–4).

RICO schemes included deliberately inducing doctors to write prescriptions and patients to take them, while intentionally turning a blind eye to diversion. The Nation has been injured by being forced to bear the direct and foreseeable costs of these schemes and their actions. The Nation's allegations do not require more than the "first step" *Hemi* mentions, and they certainly do not require going "well beyond the first step" as the theory of liability in *Hemi* required. *Id.* at 10.

Meanwhile, in *Holmes*, market manipulation caused share prices to drop, leading to broker-dealer bankruptcies, customers whose funds had been invested in other securities to experience losses from the broker-dealers bankruptcies, and then Securities Investor Protection Corp. (SIPC) being forced to pay claims for those investors' losses. 503 U.S. at 262–64. SIPC then sued the market manipulators in an attempt to recover cost of the claims paid out to the customers of the liquidated broker-dealers who had not owned any of the stocks subject to the market manipulation, but rather were merely trapped in failing broker-dealers. *Id.* at 263–64.

The convoluted connection between the actions and the harm in *Holmes* distinguishes it from the present case. Here, the objective of the RICO schemes was to manipulate doctors, pharmacies, regulators, and members of the public to encourage opioid use and addiction, and to allow or at least turn a blind eye to the resulting diversion, which directly caused the Nation to increase its expenditures both for the processing and payment of opioid prescriptions and bearing the costs of the opioid epidemic, including emergency and treatment services, repairing damage to emergency equipment and vehicles, and other medical costs. There is no attenuated chain of causation.

Further, the existence of two categories of direct victims—those who suffer *personally*, and those who suffer *economically*—is no bar to either standing or causation for the one who suffers economically, for the reasons stated above. *See* §§ I, III, *supra*. The policy interests

underlying the direct injury requirement favor allowing the Nation's claim to proceed.

Therefore, the first and third inquiries in *Holmes* weigh in favor of finding proximate cause.

The Nation's costs are also directly linked to the express purpose of Defendants' criminal RICO activities—the increased demand for, use of, and addiction to opioids. This direct link between criminal RICO activity and the injury, as opposed to legal activity, separates the case from *City of Cleveland v. Ameriquest Mortgage Securities*, 615 F.3d 496 (6th Cir. 2010). There, the Sixth Circuit held that though there may have been negative consequences from defendants' legal activities in financing the subprime mortgage market, the plaintiff had failed to directly link a wide variety of results of the subprime mortgage crisis to defendants' actions. *Id.* at 504. Here, by contrast, the illegal RICO misconduct the Nation alleges matches the harm suffered. Defendants engaged in a fraudulent scheme to promote the widespread over-prescription, over-purchase, and over-consumption of opioids, and simultaneously fostered large-scale diversion of opioids, thereby creating the addiction problem the Nation is forced to spend money to combat.

Similarly, the Nation's harm is not "exclusively derivative" of its Members' injuries.

The costs that the Nation has incurred as a result of Defendants' enterprises are not merely derived from the physical injury of particular persons, but instead are direct injuries to its revenue-generating functions and, in addition, the collective harm imposed on the community. Defendants' conduct was designed to and did cause over-prescription, over-purchase, and over-consumption of opioids which generated an opioid crisis in the Nation. It is that crisis which has caused the Nation to incur direct costs. The Nation's harm is the pecuniary injury incurred specifically in an attempt to address the opioid crisis, along with the lost revenue and funds the crisis has wrought. The Nation seeks to recover its own damages, both its own funds spent and funds not taken in, and does not "stand in the shoes of nonpurchasing customers" or a business

competitor. See Pik-Coal Co. v. Big Rivers Elec. Corp., 200 F.3d 884, 889 (6th Cir. 2000) (citation omitted). Nor does the Nation seek to recover monies for health insurance plan members required to pay increased health insurance premiums as a result of other smokers. Perry v. Am. Tobacco Co., 324 F.3d 845, 849 (6th Cir. 2003). If the Nation cannot recover for these injuries, there is no other, more direct plaintiff that will be able to vindicate the Nation's important rights. Therefore, the second inquiry under *Holmes* is satisfied because there is no risk of overlapping or duplicative damages for the claims the Nation pursues. Cf. Ill. Brick Co. v. Illinois, 431 U.S. 720 (1977).

The Nation has alleged injuries in a detailed Complaint that were directly caused by, and the intended result of, Defendants' conduct. Its claims should be allowed to proceed. See *Trollinger*, 370 F.3d at 619 (6th Cir. 2004).

2. The Complaint Alleges an Injury to "Business or Property."

Contrary to Defendants' assertions otherwise, the Nation has alleged numerous concrete injuries to its business or property as a result of Defendants' RICO violations.³¹¹ These include, but are not limited to, substantial losses of money and property vis-à-vis increased law enforcement and public works expenditures, increased emergency and treatment services, damage to emergency equipment and vehicles, the processing and payment of fraudulent prescriptions, other increased medical costs, lost tax revenue, and injury to the health and welfare of the Nation's citizens.³¹²

³¹¹ Distributors and Marketing Defendants bring largely repetitive arguments, such that these arguments are addressed in this Consolidated Opposition in conjunction with one another. See MB at 25–27. Similarly, Generic Marketing Defendants cite to the briefing in Summit County to argue that there is "no cognizable RICO injury," GM at 22, and, as previously stated, Pharmacies also cite to the briefing in Summit County, and to various arguments proffered by Marketing Defendants and Distributors, PB at 7 & n.7. To the extent an argument is not unique to a particular Defendant, the Nation cites to Distributors' brief herein.

312 See, e.g., Am. Compl. ¶¶ 351, 378, 406; see also id. ¶ 22, 274–94 (listing aspects of the Nation's damages).

The Nation does not, as Defendants allege, plead injuries that rely on personal losses. Injury to property has been interpreted in the antitrust context as "anything of material value owned or possessed," *Reiter v. Sonotone Corp.*, 442 U.S. 330, 338 (1979)—namely, any form of economic loss. "Money, of course, is a form of property." *Id.*; *see also Jackson v. Sedgwick Claims Mgmt. Servs., Inc.*, 731 F.3d 556, 563 (6th Cir. 2013) (en banc) (courts look to antitrust statutes in construing RICO).

In one representative case involving union health insurance trusts seeking to recover medical expenses paid by them for beneficiaries' smoking-related illnesses from tobacco companies, this Court found that the plaintiffs had sufficiently alleged injury to their "business or property" by alleging that the defendants' conduct "required them to incur significant costs and expenses attributable to tobacco-related diseases." *Iron Workers Local Union No. 17 Ins. Fund v. Philip Morris Inc.*, 23 F. Supp. 2d 771, 791 (N.D. Ohio 1998). Notably, in so finding, the Court held "that plaintiff's injuries are distinct from the personal injury claims of smokers." *Id.* 313 The Nation's injuries here, as detailed below, are similarly distinct.

In an effort to demonstrate otherwise, Defendants almost entirely rely on *Jackson v*. *Sedgwick Claims Management Services*, 731 F.3d 556, 562 (6th Cir. 2013) (en banc). However, the *Jackson* decision does not support Defendants' conclusions. In *Jackson*, the Court addressed a claim that plaintiffs "were legally entitled to receive certain benefits *mandated by statute as a consequence of their personal injuries.*" *Id.* at 566 (emphasis added). The Court evaluated whether workers' compensation benefits satisfied the statutory language, and found in the

³¹³ Defendants rely on the Seventh Circuit's opinion in *Doe v. Roe*, 958 F.2d 763, 767 (7th Cir. 1992), for the proposition that the terms "business or property" are words of limitation. As noted by this Court in *Iron Workers*, the *Doe* court focused on financial losses to a plaintiff who suffered a personal injury and harms that were purely derivative of that personal injury. *See Iron Workers*, 23 F. Supp. 2d at 791 n.40 (citing concern in *Doe* that "[m]ost personal injuries—loss of earnings, loss of consortium, loss of guidance, mental anguish, and pain and suffering, to name a few—will entail pecuniary consequences" (citation omitted)). That is not the case here.

³¹⁴ The *Jackson* decision was also limited insofar as the Court found that the RICO theory advanced by the plaintiffs threw off the viability of statute statutory workers' compensation schemes. *Jackson*, 731 F.3d at 568.

³¹⁵ See, e.g., Am. Compl. ¶¶ 22, 351, 378, 406.

³¹⁶ See also State Farm Mut. Auto. Ins. Co. v. Vital Cmty. Care, P.C., No. 17-11721, 2018 WL 2194019, at *6 (E.D. Mich. May 14, 2018) (distinguishing Jackson because State Farm sought damages for money paid for fraudulent claims); State Farm Mut. Auto. Ins. Co. v. Warren Chiropractic & Rehab Clinic P.C., No. 4:14-CV-11521, 2015 WL 4724829, at *12 (E.D. Mich. Aug. 10 2015) (Jackson distinguishable "because it is not the insured seeking to recover from the insurance company for his or her injuries, but rather the insurance company seeking to recover from the medical providers for purportedly fraudulent claims."); State Farm Mut. Auto. Ins. Co. v. Universal Health Grp., Inc., No. 14-10266, 2014 WL 5427170, at *8 (E.D. Mich. Oct. 24, 2014) ("Jackson does not bar a corporation that sells insurance covering personal injury claims from bringing a RICO suit, because the injuries alleged in relation to an enterprise seeking fraudulent reimbursements for services performed are to the business or property of the corporation."); Allstate Ins. Co., v. Med. Evaluations, P.C., No. 13-14682, 2014 WL 2559230, at *1 (E.D. Mich. June 6, 2014):

⁽Unlike the employee-plaintiffs in *Jackson*, Allstate is not seeking to recover for personal injuries in this action. . . . Allstate is seeking to recover for alleged injuries to both its property and its business—injuries that arose when the Defendants allegedly fraudulently induced Allstate to pay large volumes of dishonest claims.);

State Farm Mut. Auto. Ins. Co. v. Kugler, No. 11-80051, 2011 WL 4389915, at *10 (S.D. Fla. Sept. 21, 2011): (Because State Farm alleges it was the direct target and recipient of fraudulent bills and related medical documentation submitted by defendants in connection with unnecessary diagnostic tests and medical procedures allegedly performed by defendants throughout [the] course of the fraudulent scheme alleged in the complaint, and that it was injured in its business or property when it paid first and third party insurance claims on behalf of its insureds in reliance on those bills and reports, the court finds the allegations of a cognizable economic injury which supports its standing to sue under RICO).

Nation alleges an injury to "business or property" under the *Jackson* analysis, which, as later explained by the Sixth Circuit, focused on the source of the injury and, in particular, whether the injury was "inextricably intertwined" with that source. *Slorp v. Lerner, Sampson & Rothfuss*, 587 F. App'x 249, 263 (6th Cir. 2014) (summary order). The injuries caused by Defendants here are not "inextricably intertwined" with individual personal injuries. Rather, the injuries impact the Nation's revenue-generating function and are direct injuries to its "business and property." 317

Relatedly, Defendants argue that the Nation cannot recovery injury for damages incurred as a sovereign because: (1) such injuries are not injuries to "business or property"; and (2) the Nation is not a "person" for purposes of such a claim.³¹⁸ Defendants are incorrect.

First, Defendants' understanding that the Nation cannot recover damages as a sovereign because the Nation cannot assert a commercial interest—but rather can only claim an injury to the general economy or the government's ability to carry out its functions—ignores the most relevant case law and misapplies a Ninth Circuit opinion.³¹⁹ Indeed, in one of the cases heavily relied upon by Defendants, the court merely held that a governmental entity could not sue under RICO "for general injury to the economy or 'to the government's ability to carry out its functions." *See Welborn v. Bank of N.Y. Mellon Corp.*, 557 F. App'x 383, 387 (5th Cir. 2014) (per curiam) (quoting *State of Hawaii v. Standard Oil Co.*, 405 U.S. 251, 265 (1972)). There, the

³¹⁷ Apart from the lack of precedential value, the other two cases cited by Defendants—*Gucwa v. Lawley*, 731 F. App'x 408, 412 (6th Cir. 2018) (summary order), and *Haw. Health & Welfare Tr. Fund for Operating Eng'rs v. Philip Morris, Inc.*, 52 F. Supp. 2d 1196, 1200 (D. Haw. 1999)—similarly do not support Defendants' conclusion that the Nation's injuries flow from personal injuries. In fact, in *Gucwa*, the court simply followed *Jackson* to dismiss RICO claims for lost workers' compensation, 731 F. App'x at 412–13, and in *Haw. Health*, the plaintiff sought to recover exclusively for the cost of medical care for the personal injury of the smokers, 52 F. Supp. 2d at 1200.

³¹⁸ See BF at 6–8.

³¹⁹ With respect to the case Defendants cite to support their claim that the Nation cannot recover for lost tax revenue, BF at 6 n.4, the Sixth Circuit addressed a distinguishable circumstance, and rejected Michigan's RICO claim based on the defendant's cheating on taxes, after "the State of Michigan ha[d] already brought [the defendant] to account for his criminal conduct," out of respect for "the interest of comity," *Mich. Dep't of Treasury v. Fawaz*, No. 86-1809, 1988 WL 44736, at *2 (6th Cir. May 9, 1988).

governmental plaintiff allegedly it lost its ability to collect title "recording fees and general damage to the integrity of the public records." *Id.* The Fifth Circuit noted that the recording systems were "grounded on the public policy of providing notice of title," thus it was "not created to serve a revenue-generating function for the states," i.e., taxes, and therefore it was "not accurate to case the [title] recording system as commercial." *Id.* This same principle has been recognized by other Circuits as well. *See City of New York v. Smokes-Sprites.com, Inc.*, 541 F.3d 425, 445 (2d Cir. 2008) (holding that "lost taxes can constitute injury to 'business or property' for purposes of RICO . . . notwithstanding that [the City's] injury did not arise from its participation in a commercial transaction"), rev'd on other grounds, Hemi Group, LLC v. City of N.Y., 559 U.S. 1 (2010); Ill. Dep't of Revenue v. Phillips, 771 F.2d 312, 314–16 (7th Cir. 1986).

Defendants also cite to *Canyon County v. Syngenta Seeds*, 519 F.3d 969 (9th Cir. 2008), to support their argument that a sovereign cannot recover under RICO. However, *Canyon County* is not binding and in any event, in *Canyon County*, the plaintiff did not allege a concrete financial loss and was not suing to abate a public nuisance, an acknowledged exception to the municipal recovery rule that the Ninth Circuit used to support its holding (and that applies only to *local* governments). *Id.* at 975–78 (further distinguishing its case, which involved public services that had been provided for illegal immigrants employed by defendants, and cases where the government is overcharged). In fact, the *Canyon County* court itself cited to a Sixth Circuit case as an example of where a sovereign may recover, *id.* at 976, and in that case, the plaintiff had alleged that the counties were injured "when they paid the allegedly excessive charges" for treatment and disposal of sewage, and the Sixth Circuit upheld the RICO claim even though the

county had arguably passed on its damages to consumers, *Cty. of Oakland v. City of Detroit*, 866 F.2d 839, 847 (6th Cir. 1989). Here, the Nation's damages include direct financial losses.³²⁰

Next, Defendants support their argument by maintaining that RICO claims must be brought by "persons," which the Nation, as a sovereign, is not.³²¹ However, as explained above, it is clear that the Nation is seeking to recover not purely for its sovereign interests, such as in its *parens patriae* capacity or for injury to its economy, but also in the Nation's proprietary capacity for losses to its own property, such that Defendants' argument is misapplied here. *Att'y Gen. of Canada v. R.J. Reynolds Tobacco Holdings, Inc.*, 103 F. Supp. 2d 134, 149 (N.D.N.Y. 2000), *judgment aff'd*, 268 F.3d 103 (2d Cir. 2001) (holding that a foreign sovereign is a "person" for RICO purposes).

3. The Complaint Adequately Alleges Predicate Acts.

The Nation has adequately alleges predicate acts in the form of mail fraud and wire fraud in connection with the Opioid Marketing Enterprise³²² and in the form of mail fraud, wire fraud, controlled substance violations, and Travel Act violations in connection with the Opioid Supply Enterprise.³²³

a. The Nation Alleges Mail and Wire Fraud.

The Nation alleges that Marketing Defendants committed mail and wire fraud in connection with the Opioid Marketing Enterprise, and that all Defendants committed the same in connection with the Opioid Supply Enterprise. Distributors, by incorporating their arguments against the Blackfeet Tribe, largely rely on a tired Rule 9(b) argument, and otherwise maintain

³²⁰ Defendants cite two other cases, but neither involved claims brought under RICO. *See Alfred L. Snapp & Son, Inc. v. Puerto Rico ex rel. Barez*, 458 U.S. 592, 601–02 (1982); *City of Cleveland v. Ameriquest Mortg. Secs., Inc.*, 621 F. Supp. 2d 513, 519 (N.D. Ohio 2009).

³²¹ See BF at 8.

³²² Am. Compl. ¶¶ 319–28, 364, 367, 373.

³²³ *Id.* ¶¶ 337–49, 386–89, 392, 396, 398–99, 406–07.

that: (1) the Nation cannot base its RICO claims on Distributors lobbying the government to increase quotas for opioids and failing to report suspicious orders, for a variety of unfounded reasons; and (2) there are no allegations that Distributors attempted "to deprive someone of money or property." Marketing Defendants and Pharmacists make similar arguments with respect to the Opioid Supply Chain Enterprise, but do not attack the Opioid Marketing Enterprise. 325

Mail fraud involves "(1) a scheme to defraud, and (2) use of the mails in furtherance of the scheme." *United States v. Jamieson*, 427 F.3d 394, 402 (6th Cir. 2005). Wire fraud consists of essentially the same elements, except that the defendant must have used the wires in furtherance of the scheme to defraud. *United States v. Daniel*, 329 F.3d 480, 486 n.1 (6th Cir. 2003). "A scheme to defraud includes any plan or course of action by which someone uses false, deceptive, or fraudulent pretenses, representations, or promises to deprive someone else of money." *Jamieson*, 427 F.3d at 402.

First, the Nation has alleged the predicate acts of mail fraud and wire fraud with the particularity required. With respect to the Opioid Marketing Enterprise, the Nation has precisely laid out the separate instances of use of the mail or wires, including by misrepresentations, concealments, and material omissions regarding prescription opioids, all while members of the enterprise knew of the fraudulent and unlawful nature of their representations. In fact, the Nation lists, in great detail, the types of materials transmitted through mail and wire facilities to perpetrate the scheme to defraud, as well as Marketing Defendants' intention that the Front Groups and KOLs would also distribute fraudulent publications.

³²⁴ BF at 8–11.

³²⁵ See MB at 56–57; PB at 7–8.

³²⁶ Am. Compl. ¶¶ 320, 322.

³²⁷ *Id*. ¶¶ 324–25.

Opioid Supply Enterprise, the Nation specifically alleges misrepresentations, concealments, and material omissions related to Defendants' mandatory reporting requirements and in furtherance of their unlawful goal of selling prescription opioids without reporting suspicious orders or diversion and when there was a duty to disclose.³²⁸ As in connection with the Opioid Marketing Enterprise, the Nation precisely lists categories of transmissions, deliveries, or shipments by Defendants through mail or wire facilities.³²⁹ And, the Nation alleges that many of the exact dates of the uses of mail and wire facilities were deliberately hidden by and are in the sole possession of Defendants.³³⁰ In sum, these allegations far exceed the requirements of Rule 9(b). See, e.g., United States v. TEVA Pharms. USA, Inc., No. 13-cv-3702, 2016 WL 750720, at *15 (S.D.N.Y. 2016) ("Ultimately, whether a complaint satisfies Rule 9(b) 'depends on the nature of the case, the complexity or simplicity of the transaction or occurrence, the relationship of the parties and the determination of how much circumstantial detail is necessary to give notice to the adverse party and enable him to prepare a responsive pleading." (citation omitted)); United States ex rel. Kester v. Novartis Pharm. Corp., 23 F. Supp. 3d 242, 258 (S.D.N.Y. 2014) (same); see also In re Porsche Cars N. Am., Inc., 880 F. Supp. 2d 801, 815 (S.D. Ohio 2012) ("Rule 9(b) may be relaxed when there has been a lack of discovery and the information needed for a plaintiff to achieve particularity is held exclusively by the opposing party—in other words, Rule 9(b) does not require a plaintiff to be omniscient." (citation omitted)).

Second, and although the Nation's RICO claims are not based only on Defendants' failure to report suspicious orders and attempts to increase the quota for prescription opioids, such allegations do give rise to RICO claims. See Jamieson, 427 F.3d at 402 (defining a scheme

³²⁸ *Id.* ¶¶ 337–38, 342–44. ³²⁹ *Id.* ¶¶ 340–41.

³³⁰ *Id*. ¶ 345.

to defraud as "any plan or course of action by which someone uses false, deceptive, or fraudulent pretenses, representations, or promises to deprive someone else of money"). Importantly, the Nation does not simply allege a "regulatory reporting failure,"³³¹ but a deliberate attempt by Defendants to hide known suspicious orders and red flags from the government. Further, Distributors' bare assertion that they "play no role in the setting of quotas" but rather, that these quotas are "based upon applications submitted . . . ,"³³³ discounts Distributors' role in forming the association for the purpose of increasing those quotas as well as their conduct to support, and cause, the same, as alleged in the Complaint. ³³⁴

Third and finally, the Nation has alleged that Defendants acted "to deprive someone else of money." *Jamieson*, 42 F.3d at 402. Specifically, the Complaint includes, but is no limited to, numerous allegations that Defendants were involved in a "scheme to defraud Federal and state regulators, the American public, and the Nation,"³³⁵ that this scheme was "to increase their profits and sales unlawfully,"³³⁶ that the scheme was "to the detriment of consumers, prescribers, and the Nation,"³³⁷ that the scheme continues to impact the Nation,³³⁸ and that but for the

³³¹ DB at 10.

³³² Additionally, the sole case to which Distributors cite in support of their argument that regulatory reporting failures cannot be the basis of a RICO claim is an out-of-Circuit decision that based its finding—that failure to report a defect under the Safety Act was not a predicate act under the mail and wire fraud statutes—on its conclusion that "the Safety Act was not meant to create the kind of duty, a breach of which would create criminal liability or civil liability under RICO statutes." *Ayres v. Gen. Motors Corp.*, 234 F.3d 514, 521–22 (11th Cir. 2000). In fact, the Eleventh Circuit recognized that "[a]mple case law support[ed] Plaintiffs' legal theory" that failure to disclose material information can be a violation of the mail and wire fraud states where a defendant has a duty to disclose. *Id.* at 521. By contrast, Defendants' violations here are precisely the types of violations intended to create such a duty.

³³³ BF at 10.

³³⁴ See Am. Compl. ¶¶ 332, 334, 340, 344, 382–83. Defendants' argument under the Noerr-Pennington doctrine, at 10, is similarly untenable because the Nation does not base its RICO claims on lobbying, as required for the doctrine to apply.

³³⁵ *Id.* ¶ 386; *see also id.* ¶¶ 322, 338–39, 371.

³³⁶ *Id.* ¶ 296; *see also id.* ¶¶ 299, 332.

³³⁷ *Id*. ¶¶ 301–02.

 $^{^{338}}$ *Id.* ¶ 309.

scheme, the Nation "would not have paid for opioid prescriptions for chronic pain and would not be bearing the costs of its current opioid epidemic." ³³⁹

For the foregoing reasons, the Nation has alleged predicate acts based on mail and wire fraud.

b. The Nation Alleges Controlled Substance Violations.

The Nation also adequately alleges that Defendants violated 21 U.S.C. § 843 (2009) "by knowingly or intentionally furnishing false or fraudulent information in, and/or omitting material information from, documents filed with the DEA." The Complaint is replete with examples and details regarding such behavior. In arguing otherwise, Distributors attempt to recast their fraudulent behavior as mere "recordkeeping violations," entirely ignoring the fraudulent behavior alleged. As pertaining to this point, the Nation incorporates the arguments contained in the opposition filed by Summit County. *See* Plaintiffs' Mem. in Opp'n. to Defs.' Motion to Dismiss, ECF No. 654 at 59–64.

Distributor Defendants cite only one case in support of their position that Section 1961(1)(D) addressing felonious concealment relates only to the concealment of drugs,³⁴¹ but that case is not on point. Rather, *United States v. Veal*, 23 F.3d 985, 988 (6th Cir. 1994), addressed only the government's proof with respect to felonious recordkeeping charges and did not address the scope of Section 1961(1)(D). In any event, Section 1961(1)(D) does not speak only about felonious concealment, but also explicitly refers to "otherwise dealing in a controlled substance."

 $^{^{339}}$ *Id.* ¶ 356.

³⁴⁰ Am. Compl. ¶ 392.c.

³⁴¹ BF at 11–12.

³⁴² Marketing Defendants separately argue that the Nation's allegations fail to satisfy Rule 9(b) as it contains only a "bare allegation" that Defendants violated this statutory provision. MB at 57. However, this argument borders on absurd, given the plethora of detail provided in the Complaint addressing Defendants' fraudulent behavior surrounding opioid diversion. *See* n.337, *supra*.

c. The Nation Alleges Travel Act Violations.

Finally, the Nation adequately alleges Defendants' predicate act of engaging in violations of the Travel Act, 18 U.S.C. § 1952 (2014), by "using the mail and facilities in interstate commerce with the intent to carry on, or facilitate the carrying on of, an unlawful activity, namely, a business enterprise involving controlled substances in violation of Oklahoma law, including Oklahoma law regarding controlled substances and Okla. Stat. tit. 15, § 761.1(E), the criminal provision of the Oklahoma Consumer Protection Act."³⁴³

Section 1952 prohibits the traveling in interstate or foreign commerce, or use of "mail or any facility in" interstate or foreign commerce, with the intent to: "(1) distribute the proceeds of any unlawful activity; or (2) commit any crime of violence to further any unlawful activity; or (3) otherwise promote, manage, establish, carry on, or facilitate the promotion, management, establishment, or carrying on, of any unlawful activity, and thereafter perform[] or attempt[] to perform" such an act. 18 U.S.C. § 1952(a) (2014). "[U]nlawful activity" includes "any business enterprise involving . . . controlled substances." *Id.* § 1952(b).

Distributors target their motion on the Nation's allegations of unlawful activity.³⁴⁴ First, Distributors maintain that the Nation has not alleged a violation of Okla. Stat. tit. 63, § 2-406(4), which establishes liability for "furnish[ing] false or fraudulent material information in, or omit[ting] any material information from, any application, report, or other document required to be kept or filed under this act, or any record required to be kept by this Act."³⁴⁵ However, as previously detailed, the Nation has included numerous, non-conclusory allegations supporting

³⁴³ Am. Compl. ¶ 392.d; *see also id.* ¶ 389.

³⁴⁴ DB at 3–5.

³⁴⁵ In attacking this statutory basis for unlawful activity, Distributors cite the general proposition that ambiguity as to the scope of criminal statutes should be resolved in favor of lenity, to state that the Travel Act should not encompass violations of the Oklahoma CSA. DB at 4. However, Distributors themselves acknowledge that the Travel Act is "not limited to" illegal drug trades through organized crime, *id.*, and the statute is worded clearly and broadly, *see*, *e.g.*, Travel Act, 18 U.S.C. § 1952(b) (2014) ("any" enterprise "*involving* controlled substances" (emphasis added)).

that Defendants, including Distributors, violated this provision. 346 Moreover, although Distributors reject the Nation's independent claim that Defendants violated Okla. Stat. tit. 63, § 2-401(1)—which prohibits "distribut[ing], dispens[ing], transport[ing] with intent to distribute or dispense, possess[ing] with intent to manufacture, distribute, or dispense, a controlled dangerous substance"—merely by stating that Distributers are registered distributors of controlled substances such that they are authorized under the FCSA to distribute opioids, 347 Distributors ignore the many allegations that they *unlawfully* distributed opioids, in *direct contravention* of their statutory and regulatory requirements. Defendants' offhand argument that they cannot be liable for persistent illegal activity because they were authorized to distribute controlled substances discounts that the authorization was solely to distribute within the confines of the law. Distributors' argument, therefore, is disingenuous. *Cf. United States v. Goldfine*, 538 F.2d 815 (9th Cir. 1976) (pharmacist registered to sell controlled substances could still be convicted of possession with intent to distribute a controlled substance and in a manner not authorized by law).

Second, Distributors state that the Nation has not alleged a violation of the Oklahoma Consumer Protection Act ("OCPA") because: (1) the Nation has not identified any "unfair or deceptive conduct"; (2) the Nation has not pled any consumer transactions involving distributors in Oklahoma; and (3) OCPA liability cannot be premised on conduct "regulated under laws administered by" a regulatory body by statute.³⁴⁸ Distributors are wrong.

The OCPA "is to be liberally construed to effectuate its underlying purpose." *Patterson* v. *Bell*, 19 P.3d 839, 846 (Okla. 2000). In accordance with this principle, a "consumer

³⁴⁶ See generally Am. Compl.

³⁴⁷ DB at 4 n.5.

³⁴⁸ BD at 4–5.

transaction" is broadly defined as the "advertising, offering for sale or purchase, sale, purchase, or distribution of any services or any property, tangible or intangible, real, personal, or mixed, or any other article, commodity, or thing of value wherever located, for purposes that are personal, household, or business oriented." 15 O.S. § 752(2). Here, the Nation has alleged that Defendants engaged in a marketing and advertising campaign that caused the Nation to incur enormous costs. This directly falls within the statutory definition of a "consumer transaction." Moreover, for the reasons discussed above, *see* § V, *supra*, the Nation has adequately alleged unfair or deceptive conduct by Distributors and all Defendants. And, the Nation did ultimately purchase, or pay for, opioids in Oklahoma and, as required, various consumers were injured as a result of Defendants' actions.³⁴⁹

Furthermore, the safe-harbor exemption cited by Defendants does not apply here, as the OCPA safe harbor "does not apply when a defendant's conduct . . . at issue is not within the scope of the agency's authority." *Sisemore v. Dolgencorp, LLC*, 212 F. Supp. 3d 1106, 1109 (N.D. Okla. 2016) (citation omitted) (where plaintiff alleged deceptive conduct with respect to product labeling and placement, and the regulatory scheme only addressed product labeling, the safe-harbor exemption did not apply). Here, the Nation alleges conduct outside the scope of regulation.

In arguing that this exemption applies, Distributors rely on case law involving a simple failure-to-warn products liability action in which the plaintiff alleged the defendant had inadequately labeled the drug and withheld information from the FDA about its risks. *See Arnett v. Mylan, Inc.*, No. 2:10-cv-00114, 2010 WL 2035132, at *3 (S.D. W. Va. May 20, 2010). Unlike the situation in *Arnett*, where it was within the agency's authority to approve the

³⁴⁹ See, e.g., Am. Compl. ¶ 350.

allegedly defective label, here it is the state-law tort system—rather than a regulatory regime—that governs when a defendant can use false, non-FDA approved information to sell its products. In any event, this Court should not apply the safe-harbor exemption prior to adequate discovery and development of the record. *See Money v. Bristol-Myers Squibb Co.*, No. 3:07-cv-1100 (FLW), 2009 WL 5216987 (D.N.J. Dec. 30, 2009) (emphasizing need for answers to fact questions before safe-harbor exemption should apply).

4. The Complaint Alleges Participation in an Enterprise.

In the Complaint, the Nation sufficiently pleads the existence of two distinct enterprises: the Opioid Marketing Enterprise and the Opioid Supply Enterprise.

In Boyle v. United States, 556 U.S. 938 (2009), the Supreme Court explained that the definition of an enterprise, which includes "any union or group of individuals associated in fact although not a legal entity," 18 U.S.C. § 1961(4) (2016), "is obviously broad," for "[t]he term 'any' ensures that the definition has a wide reach, and the very concept of an association in fact is expansive," 556 U.S. at 944 (citations omitted). A RICO enterprise, the Court reiterated, "reaches 'a group of persons associated together for a common purpose of engaging in a course of conduct." Id. (quoting Turkette, 452 U.S. at 580). Thus, a RICO enterprise "is proved by evidence of an ongoing organization, formal or informal, and by evidence that the various associates function as a continuing unit." *Turkette*, 452 U.S. at 583. But, the Court further explained, to satisfy these requirements, "a group need not have a hierarchical structure or a 'chain of command'; decisions may be made on an ad hoc basis and by any number of methods. . . . Members of the group need not have fixed roles. . . . [and] [t]he group need not have a name, regular meetings, dues, established rules and regulations, disciplinary procedures, or induction or initiation ceremonies." Boyle, 556 U.S. at 948. The Sixth Circuit has recognized Boyle's broad construction, even noting that a district court's concern about allowing "mirrorimage, ill-motivated activity of normal business conduct" to establish an enterprise was "not well founded and ignore[d] the statutory requirement of liberal construction to effectuate RICO's remedial purposes." *Ouwinga v. Benistar 419 Plan Servs., Inc.*, 694 F.3d 783, 794 (6th Cir. 2012); *see also id.* at 794–95 (finding complaint sufficient to infer existence of an enterprise where it delineated "specific roles and relationships of" defendants, alleged the time period during which the enterprise functioned, and alleged "it functioned for the common purpose of promoting a fraudulent welfare benefit plan to generate commissions and related fees").

As set forth below, the Nation's allegations far exceed those found adequate by the Sixth Circuit, and satisfy the requirements set forth by the Supreme Court in *Boyle*.

a. The Complaint States That Marketing Defendants Formed the Opioid Marketing Enterprise.

Marketing Defendants argue that this Court should dismiss all claims based on a fraudulent marketing scheme, including the Nation's allegations concerning the RICO Opioid Marketing Enterprise, because of a failure to plead with the particularity required under Rule 9(b).³⁵⁰ The crux of Marketing Defendants' argument is that the Complaint does not identify any doctor who allegedly heard the false statements.³⁵¹ Generic Manufacturers proffer similar arguments, and separately maintain that there can be no allegations of false marketing as to Generic Manufacturers, as they do not market opioids.³⁵² For the reasons discussed in addressing Defendants' Rule 9(b) arguments, *see* § V, *supra*, Defendants are incorrect, and the Nation has more than adequately alleged the behavior and elements to support the Opioid Marketing Enterprise.

³⁵⁰ See MB at 49, 50–55.

³⁵¹ See MB at 50–55.

³⁵² See GB at 8–12.

b. The Complaint States That Defendants Formed the Opioid Supply Enterprise.

The Nation has also adequately alleged the existence of the Opioid Supply Enterprise. First, the Nation has adequately pled that Defendants shared a common purpose, including "vastly increasing their respective profits and revenues by exponentially expanding a market that the law intended to restrict," "154 "unlawfully increasing sales, revenues, and profits by fraudulently increasing the quotas set by the DEA that would allow them to benefit collectively from a greater pool of prescription opioids," and "increasing the quota for and profiting from the increased volume of opioid sales in the United States, including but not limited to creating a market for non-medical use of opioids of epidemic proportions." The Nation further described precisely how Defendants formed that common purpose vis-à-vis connections made as a result of participation in the Healthcare Distribution Alliance ("HDA"), and using the HDA "to form the systematic links and interpersonal relationships of the Opioid Supply Chain Enterprise and to assist the Defendants in engaging in the pattern of racketeering activity." These allegations establish the common purpose as well as the circumstances necessary to infer an agreement. See Twombly, 550 U.S. at 557.

Contrary to Distributors' assertion that the Nation, while alleging that Marketing

Defendants conspired with one another, does not allege the same with respect to Distributors, 359

the Nation alleges with particularity that all "Defendants worked together," 360 that "Defendants

³⁵³ The Generic Manufacturers simply cite to the briefing in *Summit County* to support their argument that there is no Opioid "Supply Chain Enterprise." *See* GM at 22. As such, the arguments below adequately address their claims.

³⁵⁴ Am. Compl. ¶ 329.

³⁵⁵ *Id*. ¶ 332.

 $^{^{356}}$ *Id.* ¶ 382.

³⁵⁷ *Id*. ¶ 330.

³⁵⁸ *Id*. ¶ 384.

³⁵⁹ BF at 12.

³⁶⁰ Am. Compl. ¶ 329.

jointly agreed to disregard their statutory duties to identify, investigate, halt, and report suspicious orders of opioids and diversion of their drugs into the illicit market,"361 that Defendants concealed their wrongdoing by "collective silence in the face of their duties to speak,"362 that they "agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud,"363 that "for the Defendants' fraudulent scheme to work, each of the Defendants had to agree to implement similar tactics,"364 and that Defendants as a whole "committed, conspired to commit, and/or aided and abetted in the commission of, at least two predicate acts of racketeering activity within the past ten years."365

Moreover, despite Distributors' claim that the Nation only alleges parallel, profit-seeking activity by Distributors, 366 the Nation alleges conduct that is not simply parallel given that Defendants engaged in cooperative, anti-competitive conduct that, as just explained, occurred in a setting suggesting an agreement, and the Nation also pled a cooperative and ongoing pattern of racketeering activity. Additionally, as explained above, see § V, supra, the Nation has alleged detailed factual information regarding Defendants' participation in the HDA, as well as the shared common purpose for which the HDA was used. Distributors' non-precedential case law cited in support of their argument that sharing a trade association does not give rise to a plausible inference of participation in a criminal enterprise, ³⁶⁷ is distinguishable and actually supports the sufficiency of the Nation's allegations, as the cases there emphasized that the allegations otherwise suggested lawful, independent conduct. See Am. Dental Ass'n v. Cigna Corp., 605 F.3d 1283, 1295 (11th Cir. 2010) (holding allegations insufficient where there was an "obvious

 $^{^{361}}$ *Id.* ¶ 332.

³⁶² *Id*.

³⁶⁴ *Id*. ¶ 391.

 $^{^{365}}$ *Id.* ¶ 396.

³⁶⁶ BF at 12.

³⁶⁷ BF at 12–13 & n.13.

alternative explanation' for each of the collective actions alleged that suggest[ed] lawful, independent conduct") (citation omitted); *Anctil v. Ally Fin., Inc.*, 998 F. Supp. 2d 127, 141–42 (S.D.N.Y. 2014) (finding that "[n]othing in the Complaint" suggested that the defendants, competitors in the mortgage industry, were working together, as the complaint only alleged the "roles each entity played in the legitimate mortgage industry," using a system to further their independent business goals, and mere membership, without more, in a trade association), *aff'd in part, rev'd in part sub nom.*, *Babb v. Capitalsource, Inc.*, 588 F. App'x 66 (2d Cir. 2015). In contrast, Defendants here actively encouraged each other's wrongdoing and remained silent in the best interest of their competitors.³⁶⁸

Second, the Nation has adequately alleged conduct in support of the Opioid Supply Enterprise and that Distributors "had '*some* part in directing the enterprise's affairs" *United States v. Fowler*, 535 F.3d 408, 419 (6th Cir. 2008).³⁶⁹

RICO liability may be imposed on any "person" who "conduct[s] or participate[s], directly or indirectly, in the conduct of [an] enterprise's affairs." 18 U.S.C. § 1962(c) (emphasis added). "Conduct" requires "direction," but "participate" is a "term of breadth." Reves v. Ernst & Young, 507 U.S. 170, 178 (1993). Therefore, "to participate . . . in the conduct of . . . affairs' must be broader than 'to conduct. . . ." Id. at 179 (citation omitted). "Of course, the word 'participate' makes clear that RICO liability is not limited to those with primary responsibility for the enterprise's affairs, just as the phrase 'directly or indirectly' makes clear that RICO liability is not limited to those with a formal position in the enterprise, but some part in directing

³⁶⁸ Distributors also maintain that the existence of routine business relationships with Marketing Defendants does not give rise to participation in an enterprise. BF at 13 & n.14. However, as previously described, the Nation alleges far more than a routine business relationship, such that Distributors' argument is misguided and the case law to which it cites is inapposite.

³⁶⁹ See BF at 13.

the enterprise's affairs is required." *Id.* To have "some part" in directing the enterprise's affairs, a defendant need only "mak[e] decisions on behalf of the enterprise or . . . knowingly carry[] them out." *Fowler*, 535 F.3d at 418. "[A]n enterprise can be operated by 'lower rung participants in the enterprise." *Id.* at 419 (citation omitted).

Here, the Nation alleges sufficient facts demonstrating that each of the Defendants made decisions about the formation and conduct of the Opioid Supply Chain Enterprise and participated in carrying out the decisions of the Opioid Supply Chain Enterprise, including but not limited to fraudulently claiming they were complying with their duties to identify, investigate, and report suspicious orders,³⁷⁰ disseminating specific false and misleading statements misrepresenting compliance with the relevant obligations and applying for increasing quotas,³⁷¹ and refusing to report and reject suspicious orders.³⁷² These allegations are sufficient under *Reves* and *Fowler*.

F. The Nation States Claims for Violations of the Lanham Act Against All Defendants.

In its Complaint, the Nation adequately alleges that Defendants at each level of the opioid supply chain used misleading statements in their commercial promotion concerning the nature, characteristics, or qualities of their goods, services, or commercial activities, which resulted in damage to the Nation. That is all that is required to state a claim under the Lanham Act. *See* 15 U.S.C. § 1125(a)(1)(B). Accordingly, Defendants' arguments for dismissal should be rejected.

³⁷⁰ Am. Compl. ¶ 333.

³⁷¹ *Id.* ¶¶ 334, 336.

 $^{^{372}}$ *Id.* ¶ 335.

1. The Heightened Pleading Standard Does Not Apply to the Nation's Lanham Act Claims.

All of Defendants' arguments for dismissal regarding the Lanham Act are premised on the mistaken assumption that the heightened Rule 9(b) pleading requirements apply to Lanham Act false advertising claims.³⁷³ Defendants fail to provide the Court with any controlling authority for this proposition, nor does such authority exist in the Sixth Circuit. *See Elcometer, Inc. v. TQC-USA, Inc.*, No. 12-cv-14628, 2013 WL 1433388, at *5 (E.D. Mich. Apr. 9, 2013) (finding no controlling Sixth Circuit authority imposing Rule 9(b) pleading requirements on Lanham Act false advertising claims); *Dow Corning Corp. v. Jie Xiao*, No. 11-10008-BC, 2011 WL 2015517, at *9 n.2 (E.D. Mich. May 20, 2011) (noting that defendants failed to identify a Sixth Circuit case requiring a heightened pleading standard for Lanham Act claims).³⁷⁴

Recent decisions show that the Sixth Circuit does not impose Rule 9(b) pleading requirements on Lanham Act claims, including claims for false advertising. *See Grubbs v. Sheakley Group, Inc.*, 807 F.3d 785, 792 (6th Cir. 2015) (applying Rule 8(a) notice pleading standard on review of Lanham Act false advertising claim); *Oaklawn Jockey Club, Inc. v. Ky. Downs, LLC*, 687 F. App'x 429, 433–34 (6th Cir. 2017) (applying Rule 8(a) pleading standard on review of Lanham Act unfair competition claim). Because all of Defendants' grounds for

³⁷³ DB at 5–9; MB at 28–29; PB at 11–12.

³⁷⁴ While Defendants neglected to fully apprise the Court of this issue, there is admittedly a split among district courts in other jurisdictions as to whether Lanham Act false advertising claims must be pled pursuant to Rule 9(b). See Wellnx Life Scis. Inc. v. Iovate Health Scis. Research Inc., 516 F. Supp. 2d 270, 283 n.2 (S.D.N.Y. 2007) ("Contrary to defendants' contention, Rule 8(a), Fed. R. Civ. P., and not Rule 9(b), Fed. R. Civ. P., applies to false advertising claims under the Lanham Act.") (citing cases); cf. Roadtec, Inc. v. Rd. Sci., LLC, No. 1:10-CV-338, 2013 WL 12123358, at *5 (E.D. Tenn. Aug. 29, 2013) (declining to apply Rule 9(b) to Lanham Act claim but requiring some degree of particularity). Nevertheless, the Nation has adequately stated a claim under either pleading standard, because where the allegations in the complaint are "complex and far-reaching, pleading every instance of fraud would be extremely ungainly, if not impossible." United States. ex rel. Bledsoe v. Cmty. Health Sys., Inc., 501 F.3d 493, 509–10 (6th Cir. 2007) (collecting cases and holding that where a plaintiff provides examples of specific fraudulent acts, it may proceed to discovery on the entire fraudulent scheme).

dismissal are based on a heightened pleading standard which does not apply here, their motions to dismiss should be denied on this basis alone.³⁷⁵

2. The Nation Has Stated a Claim Against Distributors.

Distributors erroneously assert that the Nation lacks statutory standing because "the Nation has not alleged—and could not allege—an injury to a commercial interest resulting from Distributors' conduct."³⁷⁶ But the complaint specifically alleges that misrepresentations by Diversion Defendants (including Distributors) about the quality and nature of their services had the practical effect of diverting patients away from hospitals and clinics run by the Nation, and the patients instead sought care from outside doctors and clinics who prescribed high doses of opioids.³⁷⁷ The Complaint further alleges that *but for* Distributor's misrepresentations regarding their prevention of opioid diversion, "patients would not have sought treatment from doctors and clinics who prescribed high doses of opioids because they would not have been able to obtain excessive and unnecessary quantities of opioids as a result of their treatment."³⁷⁸ These allegations constitute a cognizable injury to the Nation's commercial interests under the Lanham Act.

Distributors also erroneously argue the Nation has failed to allege an "injury flowing directly" from the Distributors' alleged misrepresentations.³⁷⁹ In the seminal case of *Lexmark International, Inc. v. Static Control Components, Inc.*, 572 U.S. 118 (2014), the Supreme Court held that a plaintiff's "injury flow[s] directly" from the defendant's misrepresentation when

³⁷⁵ If, however, the position advocated by Defendants is adopted, it would depart from the settled requirements of *Iqbal/Twombly* and create new legal precedent for pleading Lanham Act claims. *See Leatherman v. Tarrant Cty. Narcotics Intelligence & Coordination Unit*, 507 U.S. 163, 168 (1993) (noting that heightened pleading standards "must be obtained by the process of amending the Federal Rules, and not by judicial interpretation.").

³⁷⁶ See DB at 6.

³⁷⁷ *See* Am. Compl. ¶ 416.

³⁷⁸ *Id*.

³⁷⁹ MB at 28.

"deception of consumers causes them to withhold trade from the plaintiff." *Lexmark*, 572 U.S. at 133. Here, the Complaint satisfies *Lexmark*'s direct injury requirement by alleging that the Nation's Members forewent doing business with the Nation's hospitals and clinics *because of* the Distributors' misrepresentations. The Nation alleges that consumers, in choosing to pursue opioid treatment, relied in part on Distributors' misleading public representations that they were taking all necessary safety precautions to monitor opioid supplies and prevent diversion. If the Distributors had not made these misleading statements, some patients would have sought treatment and services from the Nation's facilities themselves.

Finally, Distributors argue their misrepresentations were not made in the context of "commercial advertising or promotion" and were instead merely statements about their regulatory compliance efforts, which Distributors claim is not enough for Lanham Act liability.³⁸³ This argument ignores the plain statutory text, which broadly prohibits misrepresentations concerning "goods, services, *or* commercial activities." 15 U.S.C. § 1125(a)(1)(B) (emphasis added). The statute provides that:

Any person who, on or in connection with any goods or services ... uses in commerce any . . . false or misleading description of fact, or false or misleading representation of fact, which . . .

(B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities,

shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

Id. at (a)(1). The inclusion of "services, or commercial activities" renders the statute sufficiently broad to cover the misrepresentations alleged in the Complaint. *See Grubbs*, 807 F.3d at 801

 $^{^{380}}$ See Am. Comp. ¶¶ 415–16.

³⁸¹ See id. ¶¶ 209, 210, 222 n.97.

³⁸² See id. ¶¶ 411–16.

³⁸³ DB at 8.

(statements regarding quality of financial services were actionable). Put differently, because Distributors' opioid distribution is a core commercial activity, their public statements about implementing rigorous and effective programs to protect the integrity of their distribution systems are clearly statements about commercial activities.

This conclusion is confirmed by the case law. Although the phrase "commercial advertising or promotion" is not defined by statute, the Sixth Circuit has held that "commercial advertising or promotion" consists of "(1) commercial speech; (2) for the purpose of influencing customers to buy the defendant's goods or services; (3) that is disseminated either widely enough to the relevant purchasing public to constitute advertising or promotion within that industry or to a substantial portion of the plaintiff's or defendant's existing customer or client base." *Grubbs*, 807 F.3d at 801. Conceding that their misrepresentations were widely disseminated, Distributors simply argue the Complaint fails to allege any false statements made by Distributors in "commercial speech" for the "purpose of influencing customers to buy [their] goods or services." *Id.* at 798. At the pleading stage, however, the Court must draw all reasonable inferences from the allegations in the complaint in favor of the plaintiff. Under that standard, there should be no question the Complaint implicates Distributors' commercial speech.

This is because "commercial speech" encompasses more than simply speech that proposes a commercial transaction. *Bolger v. Young Drug Prods. Corp.*, 463 U.S. 60, 66 (1983). Here, Distributors' misrepresentations constitute commercial advertising and/or promotion because they referenced a specific product or service and were motivated by economic and financial gain. In addition, the Complaint identifies, *inter alia*, specific statements by Distributors, all of which reference opioid distribution and were made in furtherance of their

³⁸⁴ See, e.g., Am. Compl. ¶¶ 233–36, 330–34, 342–344, 350.

opioid distribution businesses.³⁸⁵ As alleged in the complaint, these misrepresentations went beyond mere puffery, and were objectively false. *See, e.g., United States ex rel. Knisely v. Cintas Corp., Inc.*, 298 F.R.D. 229, 243 (E.D. Pa. 2014) (refusing to dismiss claim where defendant allegedly misled customers about its quality control and adherence to "stringent... security practices"). Accordingly, Distributor Defendants' Motion to Dismiss the Nation's Lanham Act claim should be denied.

3. The Nation Has Stated a Claim Against Marketing Defendants.

Marketing Defendants' central argument is that their products or services are not in direct competition with the products or services offered by the Nation's hospitals and clinics, and therefore the Lanham Act does not apply.³⁸⁶ Even if this assertion were factually correct, in *Lexmark*, the Supreme Court rejected the argument that only direct competitors have statutory standing to sue under the Lanham Act. *Lexmark*, 572 U.S. at 136 ("a rule categorically prohibiting all suits by noncompetitors would read too much into the Act's reference to 'unfair competition.'" (citation omitted)). In rejecting the same narrow "direct competitor" test advanced by the Marketing Defendants here, the *Lexmark* Court concluded that a plaintiff is authorized to sue under the Lanham Act where it brings its case as an entity engaged in commerce within the control of Congress. *Id.* As the Nation, through its hospitals and clinics, is engaged in commerce, its Lanham Act claim is properly brought against Marketing Defendants.

Next, Marketing Defendants argue that the Nation has not alleged any commercial harm.³⁸⁷ For the reasons discussed above, *see* § IV, *supra*, the Nation has sufficiently alleged it suffered commercial harm.³⁸⁸ Marketing Defendants' attempt to portray the Complaint's

³⁸⁵ See id. ¶¶ 222 n.97 (AmerisourceBergen), 209 (Cardinal), 210 (McKesson).

³⁸⁶ MB at 28–29.

³⁸⁷ MB at 28–29.

³⁸⁸ See also Am. Compl. ¶¶ 105–109, 117, 121–123, 128, 131, 142–143, 146, 416.

allegations as solely referring to the health of the Nation's Members is disingenuous.³⁸⁹ The Nation alleges that Marketing Defendants' false statements about the relative advantages and low risks of their opioid products caused more people to seek opioids, rather than to seek more traditional care at a hospital.³⁹⁰

4. The Nation Has Stated A Claim Against Pharmacies.

Pharmacies also contend the Nation has not alleged any "commercial advertising or promotion' by any of the [Pharmacies]."³⁹¹ Again, this argument overlooks numerous well-pled allegations in the Complaint that reference and quote examples of misleading statements by the Pharmacies promoting the quality of their pharmacy services and their brands. For example, the Complaint alleges that in recent years Walgreens has published promotional materials claiming it was "Lead[ing] [the] Fight Against Prescription Drug Abuse "³⁹² Walgreens' promotional claim to be "leading the fight" against the opioid epidemic is demonstrably false. ³⁹³ In fact, in recent years the DEA has shuttered Walgreens stores, and federal and state law enforcement agencies have investigated and imposed fines on Walgreens relating to the company's failure to comply with laws designed to prevent opioid diversion. ³⁹⁴ The same is true for the other Pharmacies, which similarly disseminated false promotional materials to the public about their supposedly state-of-the-art pharmacy services designed to protect consumers—while at the same time facing large penalties relating to their failure to comply with federal and state laws and regulations. ³⁹⁵

³⁸⁹ MB at 28–29.

³⁹⁰ *See* Am. Compl. ¶ 416.

³⁹¹ See PB at 11–12.

³⁹² Am. Compl. ¶ 242.

³⁹³ See, e.g., id. ¶¶ 245, 253–55.

 $^{^{394}}$ *Id.* ¶¶ 245, 253–55.

³⁹⁵ *Id.* ¶¶ 241, 243–52, 256. For example, Defendant Walmart advertised that "the health and safety of our patients is a critical priority" and promoted Walmart's steps to address prescription drug abuse, including "comprehensive"

Pharmacies contend that these well-pled allegations can be disregarded because they are "not about the 'nature, characteristics [or] qualities' of the goods (i.e. the prescription opioids) themselves."396 Of course, the fact that Pharmacies did not advertise about the characteristics of "prescription opioids themselves" is irrelevant. The Lanham Act is not limited to misrepresentations regarding products. As discussed above, the Act prohibits Pharmacies from using any misleading representation of fact in connection with "goods, services, or commercial activities." 15 U.S.C. § 1125(a)(1)(B) (emphasis added). Pharmacies' statements were made in connection with their commercial activities, and are therefore encompassed by the Lanham Act. That the content of the statements touched upon an important topic of public health (the opioid crisis) is also beside the point. See Bolger, 463 U.S. at 67–68 (informational pamphlets constituted commercial speech notwithstanding the fact that they contained discussions of important public health issues); see also Semco, Inc. v. Amcast, Inc., 52 F.3d 108, 112 (6th Cir. 1995) ("Speech need not closely resemble a typical advertisement to be commercial."); Duro Corp. v. Canadian Standards Ass'n, No. 1:17 CV 1127, 2017 WL 6326862, at *5 (N.D. Ohio Dec. 11, 2017) (statement of certification of compliance with government consumer safety standards is commercial speech). The Complaint sufficiently alleges that Pharmacies, to further their economic interests, made false or misleading statements in the course of promoting their purported activities and achievements in the area of combating opioid diversion.³⁹⁷

Pharmacies also argue in passing that their statements were not sufficiently misleading to materially deceive a "substantial portion" of the consumer audience.³⁹⁸ That is incorrect or

³⁹⁶ See PB at 12.

³⁹⁷ Am. Compl. ¶¶ 240–44.

³⁹⁸ See PB at 12.

unavailing for two reasons. First, the Nation did, in fact, allege that the public was materially deceived, and this allegation must be taken as true for purposes of a motion to dismiss. ³⁹⁹

Second, disputed factual issues regarding the extent of the public deception cannot be resolved on a motion to dismiss. *Wysong Corp. v. APN, Inc.*, 889 F. 3d 267, 271 (6th Cir. 2018) ("At the motion-to-dismiss stage . . . [the court] ask[s] whether the facts in the complaint support a plausible inference that the challenged advertisements in fact misled a significant number of reasonable consumers."); *Ameritox, Ltd. v. Millennium Labs., Inc.*, 889 F. Supp. 2d. 1304 at 1316-17 (M.D. Fla. 2012) (holding that allegations that consumers were at least in part influenced by supposedly misleading statements met the pleading requirements for deception and materiality).

Finally, Pharmacies challenge the allegations regarding causation. The Supreme Court instructs that "a plaintiff suing under § 1125(a) ordinarily must show economic or reputational injury flowing directly from the deception wrought by defendant's advertising; and that occurs when deception of consumers causes them to withhold trade from the plaintiff." *Lexmark*, 572 U.S. at 133 (2014). The Nation alleges precisely this kind of injury in its Complaint. Pharmacies have not negated and cannot negate—indeed, *may not seek to negate* at the pleading stage—the Complaint's allegations that, by promoting their fake efforts to combat opioid abuse, Pharmacies favorably influenced patients to use the chain Pharmacies' services rather than the competing facilities and treatment options offered by the Nation's hospitals and clinics. *See Animal Legal Defense Fund v. HVFG LLC*, 939 F. Supp. 2d 992, 998 (N.D. Cal. 2013) (reasoning that a competitor's statement that its product is "humane," if in fact it were not, would

³⁹⁹ Am. Compl. ¶¶ 415–17.

⁴⁰⁰ See PB at 12.

⁴⁰¹ Am. Compl. ¶ 416.

plausibly disadvantage its humane competitor, and holding that such an allegation satisfies the causation prong of a Lanham Act claim); *Ameritox*, 889 F. Supp. 2d. at 1317 (finding that plaintiff met the Lanham Act's pleading requirements by alleging that healthcare providers were at least in part persuaded to do business with defendant based on defendant's deceptive implication it was acting altruistically).

5. The Nation Has Stated a Claim Against Generic Manufacturers.

Generic Manufacturers are not shielded from liability under the Lanham Act merely because they sell generic opioids. The Nation's Lanham Act claims against Generic Manufacturers are premised on their misrepresentations concerning the safety and efficacy of opioids, as well as their misrepresentations concerning the prevention of diversion. The Complaint alleges that Generic Manufacturers failed to communicate effectively and adequately the warnings on their products' labels to physicians and patients, and failed to counter known misrepresentations made by the name-brand opioid manufacturers in their own advertising and promotions—even though Generic Manufacturers counted on these misrepresentations by their co-conspirators (and benefitted from them) in selling their generic opioid products. The Complaint also alleges that Generic Manufacturers made verifiably false statements regarding their efforts to prevent diversion. The Court must disregard Generic Manufacturers' assertion in their brief that they do not "promote or advertise their products," because it runs counter to the well-pled allegations in the Complaint, which must be accepted as true on a motion to dismiss. On the season of the season of

⁴⁰² See Am. Compl. ¶¶ 155, 157–58.

⁴⁰³ See id. ¶¶ 208, 211, 413, 416.

⁴⁰⁴ See id. ¶ 160.

manufacturers also follow a normal industry practice by promoting their products primarily by distribution of catalogs to wholesalers, hospitals, and retail pharmacies").

Finally, Generic Manufacturers freely accept and rely on the benefits and publicity of the name-brand manufacturers' promotional statements and advertising to consumers—including the name-brand manufacturers' instances of misbranding and misrepresentations alleged in this case—but Generic Manufacturers seek to avoid liability arising from those same misrepresentations. The Nation alleges that Generic Manufacturers knew that the Brand-Name Manufacturers' advertising and promotional statements were misleading, but Generic Manufacturers did nothing to try to reduce their participation or complicity in disseminating false information. Generic Manufacturers have not cited any law that prohibits the Nation's well-pled Lanham Act claim in these circumstances.

⁴⁰⁵ Am. Compl. ¶¶ 157–61.

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LOCAL RULE 7.1(F) CERTIFICATION

Pursuant to Case Management Order Number Six (Dkt. 770, July 23, 2018) and the Court's subsequent Order Regarding Page Limitations for Briefing on Motions to Dismiss (Dkt. 791, July 26, 2018), the Nation is permitted to file a consolidated opposition to Defendants' motions to dismiss totaling 185 pages. This brief adheres to that limit.

/s/ Jenna A. Hudson

Jenna A. Hudson

CERTIFICATE OF SERVICE

I, Jenna A. Hudson, hereby certify that the foregoing document was served via the Court's ECF system to all counsel of record.

/s/ Jenna A. Hudson
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